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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: INSULIN PRICING
LITIGATION

This Document Relates to:
Class Track

Case No. 2:23-md-03080

MDL No. 3080

Judge Brian R. Martinotti
Judge Rukhsanah L. Singh

DEMAND FOR JURY TRIAL

AMENDED CONSOLIDATED CLASS ACTION COMPLAINT

TABLE OF CONTENTS

I.	INTRODUCTION	2
II.	PARTIES	16
A.	Plaintiffs	16
B.	Manufacturer Defendants	19
C.	PBM Defendants	20
1.	CVS Caremark	20
2.	Express Scripts	27
3.	OptumRx	37
D.	Rebate Aggregator Defendants	45
III.	JURISDICTION AND VENUE.....	48
IV.	DRUG PRICING IN THE UNITED STATES	50
A.	Entities Involved in Drug Pricing.....	50
B.	TPP Plaintiffs and TPP Class Members Employ PBMs as Agents and/or Fiduciaries and Directly Purchase from PBMs and Their Mail Order Pharmacies	54
C.	Other Direct Purchaser Plaintiffs Directly Purchase from Manufacturer Defendants	59
D.	PBM Defendants and Manufacturer Defendants Have Ample Opportunity to Coordinate Pricing	60
E.	Defendants' Manipulation of PBM Incentives and Resulting Profits	63
F.	Defendants Downplay the Pricing and Kickback Scheme for Insulin Drugs and Its Resulting Harms to Congress	77
G.	Recent Government and Regulatory Investigations Spotlight Defendants' Conduct	84

H.	While Government and Public Scrutiny Has Recently Forced Some Changes, Prices for Insulin Drugs Remain High from Defendants' Scheme and Plaintiffs and Class Members Have Not Been Compensated for Their Damages	95
V.	INSULIN DRUGS.....	101
A.	Diabetes: The Disease and Demographics	101
B.	The Origins of Insulin Treatment.....	105
C.	Insulin Treatment Landscape	110
D.	Climbing Insulin List Prices.....	111
E.	Eli Lilly, Novo Nordisk, and Sanofi Have Sold Increased Spreads to PBMs in Exchange for (or as a Kickback for) Preferred Formulary Status	129
F.	Manufacturer Defendants Have Engaged in "Bundling" Insulin Drugs with GLP-1 Drugs in Furtherance of Their Scheme To Drive Up the Price of Insulin Drugs.	141
G.	The Artificial Inflation of List Prices Harms Plaintiffs and Class Members	143
VI.	INTERSTATE TRADE AND COMMERCE	148
VII.	ANTITRUST AND RICO INJURY	149
VIII.	TOLLING OF THE STATUTE OF LIMITATIONS	151
A.	Continuing Violations/Separate Accrual Doctrine	151
B.	Fraudulent Concealment Tolling.....	151
C.	Estoppel	151
D.	Relation Back/ <i>American Pipe</i> Tolling	152
IX.	CLASS ACTION ALLEGATIONS	152
X.	CLAIMS FOR RELIEF.....	159

A. COUNT ONE VIOLATIONS OF RICO, 18 U.S.C. § 1962(c).....	159
1. Defendants are Culpable “Persons” Under RICO	161
2. The Manufacturer-PBM Insulin Pricing RICO Enterprises.....	161
3. The Manufacturer-PBM Insulin Pricing RICO Enterprises’ Use of the U.S. Mails and Interstate Wire Facilities	173
4. Conduct of the RICO Enterprises’ Affairs	176
5. Defendants’ Pattern of Racketeering Activity	179
6. Defendants’ Motive.....	186
7. Damages Caused by Defendants’ Pricing Scheme	187
B. COUNT TWO VIOLATIONS OF RICO, 18 U.S.C. § 1962(d)	191
C. COUNT THREE VIOLATION OF THE ROBINSON-PATMAN ACT, 15 U.S.C. § 13(c).....	193
XI. DEMAND FOR JUDGMENT	198
XII. JURY DEMAND.....	199

Plaintiffs Local No. 1 Health Fund (“Local 1 Health Fund”) and Plan of Benefits for the Local No. 1 Health Fund (“Local 1 Health Fund Plan”) (together “Local 1”) and Local 837 Health and Welfare Plan (“Local 837”) (collectively, the “TPP Plaintiffs”)¹ and FWK Holdings, LLC (“FWK”) and Professional Drug Company, Inc. (“PDC”) (together, the “Other Direct Purchaser Plaintiffs”) (collectively, the TPP Plaintiffs and Other Direct Purchaser Plaintiffs are referred to as “Plaintiffs”), on behalf of themselves and all others similarly situated, file this Amended Consolidated Class Action Complaint against defendants Eli Lilly and Company (“Eli Lilly”), Novo Nordisk Inc. (“Novo Nordisk”), and Sanofi-Aventis U.S. LLC (“Sanofi”) (collectively, Eli Lilly, Novo Nordisk, and Sanofi are referred to as the “Manufacturer Defendants”), Defendants CVS Health Corporation, Caremark, LLC, CaremarkRx LLC, CaremarkPCS Health, LLC, and Zinc Health Services, LLC (together, “CVS Caremark”), Evernorth Health, Inc., Express Scripts, Inc., Express Scripts Administrators, LLC, ESI Mail Pharmacy Services, Inc., Express Scripts Pharmacy Inc., Medco Health Solutions, Inc., and Ascent Health Services LLC (together, “Express Scripts”), UnitedHealth Group, Inc., Optum, Inc., OptumRx, Inc., OptumInsight, Inc., and Emisar Pharma Services LLC (together, “OptumRx”) (collectively, CVS Caremark, Express Scripts, and OptumRx are

¹ “TPPs” refers to third-party payors like health plans that pay for prescription drugs for their plan members.

referred to as the “PBM Defendants”) (together, the Manufacturer Defendants and PBM Defendants are referred to as “Defendants”),² alleging the following based on (a) personal knowledge, (b) the investigation of counsel, and (c) information and belief.

I. INTRODUCTION

1. Plaintiffs, direct purchaser health benefit providers and other direct purchasers of Insulin Drugs³ from Defendants, on behalf of themselves and similarly situated Class members, bring this proposed class action against the three primary drug manufacturers of diabetes medications—Eli Lilly, Novo Nordisk, and Sanofi—and the three pharmacy benefit managers (“PBMs”) that control approximately 80% of the U.S. prescription drug market—CVS Caremark, Express Scripts, and OptumRx—for the fraudulent, artificial, and unlawful inflation of the prices of Insulin Drugs in the United States between January 1, 2009 and continuing through the date of the Court’s Order on Plaintiffs’ motion for class certification (“Class Period”).

² Zinc Health Services, LLC (“Zinc”), Ascent Health Services LLC (“Ascent”) and Emisar Pharma Services LLC (“Emisar”) together are “Rebate Aggregator Defendants.”

³ “Insulin Drugs” or “Insulins” means Humulin, Novolin, Apidra, Fiasp, Humalog, Novolog, Basaglar, Lantus, Levemir, Toujeo, and Tresiba.

2. Diabetes is an epidemic in the United States. An estimated 38.4 million people in the United States—11.6% of the population—are living with Type 1 or Type 2 diabetes.⁴

3. The market for the production and sale of Insulin Drugs in the United States is highly concentrated. Manufacturer Defendants collectively manufacture approximately 90% of the Insulin Drugs sold in the United States. The PBM market is also highly concentrated. The three PBM Defendants alone make up roughly 80% of the market share and negotiate more than half of all drug rebates.

4. The insulin market should be extremely competitive. Insulins have existed for decades and cost very little to produce. The Insulin Drugs, which are produced and sold by Manufacturer Defendants, are largely interchangeable within their categories (rapid-acting or long-acting). Accordingly, patients generally do not need to take one specific brand of insulin over the other to treat their diabetes, and health plans largely do not need to cover all the Insulin Drugs. Such market conditions should yield lower insulin costs for health plans and diabetics. Because of Defendants' pricing and kickback scheme described below, such competition has not occurred. Instead, Defendants have colluded to *raise* the prices for Insulin Drugs, thereby harming Plaintiffs and Class members.

⁴ See National Diabetes Statistics Report, Centers for Disease Control (May 15, 2024), <https://www.cdc.gov/diabetes/php/data-research/index.html>.

5. The price of Insulin Drugs set by the manufacturer—the *list price* (also known as the wholesale acquisition cost or “WAC”)—provides the basis for all prices set in the distribution chain. Manufacturer Defendants, together with PBM Defendants, employed a scheme to widen the spread between the publicly available list price and another secret price, the *net price*—or the price after subtracting rebates and discounts that Manufacturer Defendants offered to PBM Defendants.

6. PBMs, including PBM Defendants, represent TPPs, including TPP Plaintiffs, and act as third-party intermediaries and/or agents on behalf of TPPs when dealing with the drug manufacturers. In this role, PBMs create and maintain a list of drugs—called a formulary—that outlines the prescription medications the health plan will cover. PBMs profit in several ways, including when they negotiate for drugs on their respective clients’ formularies through rebates, usually by retaining a percentage of the list price and rebates.

7. When two or more branded medicines fall into the same therapeutic category and have similar effectiveness and safety profiles (as is the case with Insulin Drugs), a PBM may sometimes exclude, or place in a non-preferred position, one of the medications in favor of another on the formulary. When a drug is excluded from a formulary or placed in a non-preferred position, health plans and their beneficiaries shoulder a greater percentage or all of the disadvantaged product’s cost. As a result,

PBM Defendants can push significant portions of the market towards or away from Manufacturer Defendants' products by virtue of the formulary decisions they make.

8. The PBMs have expertise and specialized knowledge in the construction of drug formularies and in negotiating the amount that health plans pay for a manufacturer's drug(s). The health plans lack that same degree of expertise on those subjects. PBMs represent to the health plans that they will use their expertise to manage the plan's formulary in the best interests of the plan so as to lower the plan's cost of drugs while providing the plans' members with cost effective access to needed drugs.

9. Health plans and plan sponsors, lacking the PBM's specialized knowledge, grant significant discretion to PBMs in how to construct a plan's formulary and the prices which the plan will pay for its members' drugs. The plans trust the PBMs to manage their formularies and have confidence that the PBMs will negotiate price with the drug manufacturers on their behalf and in their best interests and the plans rely on the PBMs to do so.

10. The PBMs represent that they will exercise their discretion in constructing the formulary to incentivize the plan members to choose drugs that will lower drug costs to the plans. In negotiating the price of the drugs that the plan will pay for drugs, the PBMs negotiate rebates or discounts from the drug manufacturers in return for favorable placement of the drug on the formulary. If the rebate or

discount is passed on to the plan by the PBM, it may lower the cost of the drug to the plan. But as alleged more specifically below, PBM Defendants often disguise the rebates or discounts as “fees” paid to PBM Defendants or their sister entities or otherwise hide and conceal these rebates or discounts from the plans and retain the rebate, discount, or purported “fees” for themselves.

11. In return for these phantom “fees” or undisclosed and hidden rebates or discounts from manufacturers, including the Manufacturer Defendants, the PBM Defendants place the manufacturer’s drug in a favored position over lower cost equally efficacious alternative drugs—such as favoring expensive brand drugs over much less expensive generic equivalent drugs.

12. The PBM Defendants and Manufacturer Defendants are aware and intend that these phantom fees and/or undisclosed rebates be hidden from health plans and not passed on to the health plans. The Manufacturer Defendants intend that these undisclosed rebates and phantom fees be paid to the PBM Defendants in exchange for more favorable placement of the Manufacturer Defendants’ drugs on the plan’s formulary over less expensive alternatives.

13. In addition, the PBM Defendants have created exclusive formularies, where only one manufacturer’s drug is included on the formulary and the plan does not cover the alternative competitive drugs at all. In order to obtain formulary exclusivity, the PBM Defendants demand and the Defendant Manufacturers

knowingly pay to the PBM Defendants hidden or disguised rebates and phantom “fees” for which no services are performed by the PBM Defendant.

14. PBMs typically make money in a multitude of ways. First, they keep the difference between what they pay retail pharmacies for drugs (a percentage of the list price plus dispensing costs) and what health plans pay them (a higher percentage of the list price plus dispensing costs). Second, PBMs extract rebates from drug manufacturers in exchange for the placement of the manufacturers’ drugs on PBM formularies and pocket a portion of the difference between a drug’s list price and the net price they negotiate with its manufacturer (through rebates and fees tied to the drugs’ list price)—i.e., the “spread” between prices. Third, PBMs sell prescription drugs to TPPs through the mail order pharmacies that they own and operate. Fourth, PBMs retain the entirety of undisclosed and/or hidden rebates and fees they receive. PBMs thus benefit both from higher list prices and larger spreads between list and net price. The higher the list price and the larger the spread between a drug’s list and net price, the larger the PBM’s profits. Given this, Defendants have created a pricing system that turns what would be normal economic competition on its head.

15. Additionally, Manufacturer Defendants have engaged in “shadow pricing,” a tactic where they tacitly agree to follow each other’s list price increases in near unison. Then, with identical list price increases, Manufacturer Defendants

need only “compete” through kickbacks to PBM Defendants in the form of enormous rebates and fees. In other words, instead of lowering their *net* prices while keeping their *list* prices constant, Manufacturer Defendants all raised their *list* prices in lockstep while keeping their *net* prices constant, as depicted below.

Figure 1: Manufacturer Defendants increase long-acting insulin list prices in lock-step

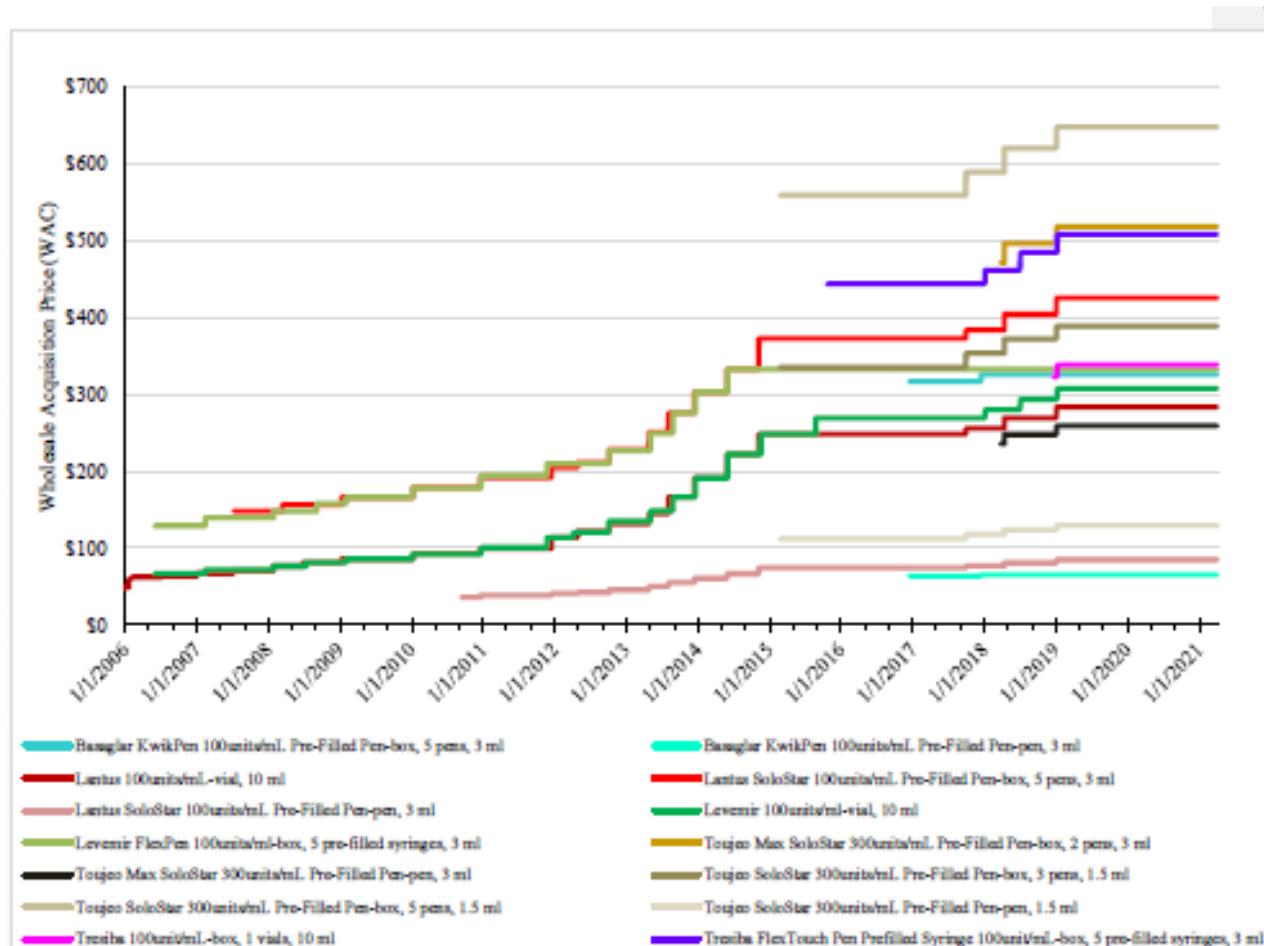
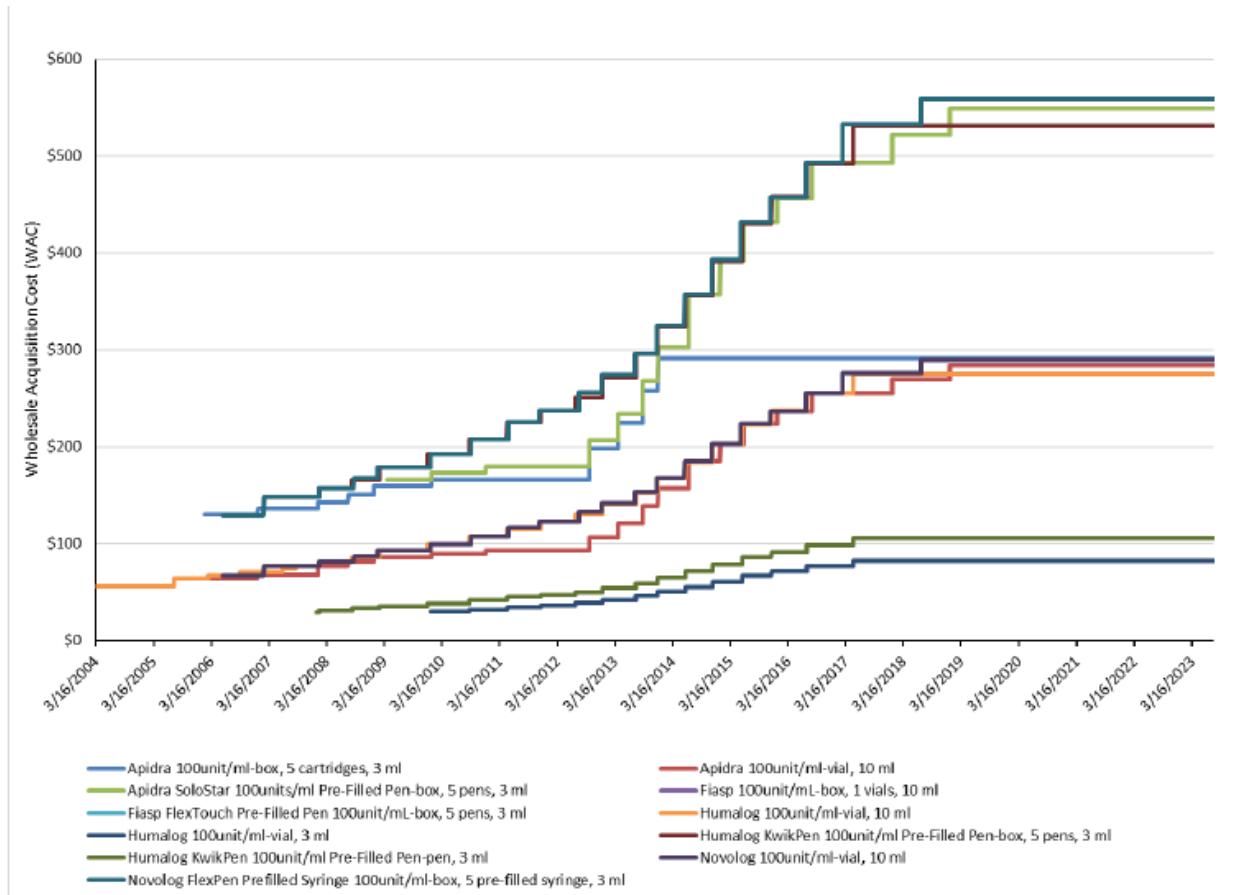


Figure 2: Manufacturer Defendants increase rapid-acting insulin list prices in lockstep



16. This perverse form of competition has yielded absurd results. As many of Manufacturer Defendants' Insulin Drugs got older and more alternatives emerged, these drugs became *more* expensive, not less. For many years, to prop up their net price, Manufacturer Defendants have resorted to aggressive list price increases—in lockstep—to make room for more and larger rebates and other payments to PBM Defendants in exchange for favorable and unwarranted formulary placement by the PBM Defendants. In a five-year period alone, the Manufacturer Defendants raised their list prices by over 150%. List prices that used to be \$75 fifteen years ago are

now between \$300 and \$700, and *nothing* about the Insulin Drugs has changed in that period; the \$600 drug is the exact same one the Manufacturer Defendants sold for \$75 years ago.

17. At the same time, as a result of the increased list prices and rebates and fees paid to the PBM Defendants, the PBM Defendants' profit-per-prescription has grown exponentially. A recent study published in the Journal of the American Medical Association concluded that the amount of money that goes to the PBMs for each insulin prescription increased by more than 150% from 2014 to 2018.⁵

18. As a result of Defendants' scheme, the list prices for the Insulin Drugs have become meaningless and divorced from net prices. They do not reflect marketplace value for the products or cutting-edge technology, nor do they reflect some increasing need to recoup investment. Rather, to the extent they are not completely arbitrary, they simply reflect the lengths to which Defendants have gone to avoid market forces and increase profits.

19. PBM Defendants solicited, and Manufacturer Defendants paid, undisclosed and hidden bribes and kickbacks not for services rendered, but rather in exchange for Manufacturer Defendants' placement of Insulin Drugs in unwarranted

⁵ Karen Van Nuys, et al., Estimation of the Share of Net Expenditures on Insulin Captured by US Manufacturers, Wholesalers, Pharmacy Benefit Managers, Pharmacies, and Health Plans From 2014 to 2018, JAMA Network (Nov. 5, 2021), <https://jamanetwork.com/journals/jama-healthforum/fullarticle/2785932>.

favorable positions on the TPPs’ “formularies.” These formularies are in reality controlled by PBM Defendants and determine whether and to what extent the nation’s health insurers and other TPPs pay for their insureds to receive life-sustaining Insulins.

20. But while this pricing scheme enormously benefits Defendants, it harms Other Direct Purchasers, TPPs, and patients. TPPs and Other Direct Purchasers pay for Insulin Drugs based on their list price. So, by creating a system where all of the competing products bear equally high list prices, Defendants have foisted the financial consequences of this perverse form of competition onto the very parties that should benefit from actual competition.

21. Defendants have told Plaintiffs, Congress, and the public that health plans are benefitting from a system of high list prices and rebates and the health plans are obtaining lower prices for the Insulin Drugs than they would absent the rebates. This narrative is false. If Defendants were required to publish a list price that approximated the true net prices, Defendants would have to start competing through significantly lower net prices, rather than significantly inflated list prices. Defendants have managed to escape the usual consequence of competition: lower prices. Their list price manipulation has enabled them to keep their net prices the same for decades, despite stiff competition. Clear, transparent pricing would force

Defendants to compete on, and therefore lower, the net price, benefiting both Plaintiffs, similarly situated Class members, and patients.

22. All of the Defendants have participated in this arms-race escalation of reported list prices and spreads. What's more, they admit it.⁶

23. Olivier Brandicourt, the former-CEO of Sanofi, acknowledged the growing gap between list price and net price in sworn testimony before the United States Senate Finance Committee:

Since 2012, the net price of Sanofi insulins has declined 25 percent. Yet patient out-of-pocket costs have continued to rise. If you take Lantus, for instance, our most prescribed insulin, the net price has fallen by 30 percent since 2012. Yet over the same period, average out-of-pocket costs have risen approximately 60 percent for patients with commercial insurance and Medicare. It is my belief that declining net prices should result in lower out-of-pocket costs for patients. But clearly, this is not always the case.⁷

24. In written remarks in connection with an April 10, 2019 U.S. House of Representatives Committee on Energy and Commerce hearing, Doug Langa, Novo Nordisk's President, similarly recognized "misaligned incentives" that have led to higher drug costs, including for insulin: "Chief among these misaligned incentives is the fact that the rebates pharmaceutical companies pay to PBMs are calculated as

⁶ Staff of S. Comm. on Fin, 116th Cong., Rep. on Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug 66 n.344 (Comm. Print 2021), <https://www.finance.senate.gov/imo/media/doc/Insulin%20Committee%20Print.pdf>.

⁷ Drug Pricing in America: A Prescription for Change, Part II, Hearing Before the S. Fin. Comm. (Feb. 26, 2019), at 16.

a percentage of WAC [list] price. That means a pharmaceutical company fighting to remain on formulary is constrained from lowering WAC price, or even keeping the price constant, if a competitor takes an increase. This is because PBMs will then earn less in rebates and potentially choose to place a competitor's higher-priced product on their formulary to the exclusion of others.”⁸

25. Defendants knew that the list prices for the Insulin Drugs served as the basis for Plaintiffs' and Class members' payments. But, the PBM Defendants still sought massive bribes and kickbacks to facilitate larger and larger spreads, and the Manufacturer Defendants still published artificially inflated list prices for the Insulin Drugs.

26. Defendants' actions harm the Class that Plaintiffs seek to represent. TPP Plaintiffs, like other TPPs in the putative Class, offer health benefits to insulin-dependent patients. One of the key benefits they provide to their members is coverage of their drug costs. When a participant orders an Insulin Drug through a PBM Defendant's mail order pharmacy, their TPP pays for that prescription based on *list* price. This formula is set out in contracts between the TPP and the PBM. Thus, these purchases are based on Manufacturer Defendants' list prices. The price

⁸ Testimony of Douglas J. Langa Novo Nordisk Inc. Before the H. Comm. on Energy & Com. Subcomm. on Oversight and Investigations at 3 (Apr. 10, 2019), <https://www.congress.gov/116/meeting/house/109299/witnesses/HHRG-116-IF02-Wstate-LangaD-20190410.pdf>.

reductions Manufacturer Defendants offer PBM Defendants *are not reflected* in the rates the TPP Plaintiffs and similarly situated Class members are charged for their covered participants' purchases from the PBM Defendants' mail order pharmacies. Thus, the larger the list price, the larger the amount the similarly situated TPPs, like the TPP Plaintiffs, are charged. Each of the Defendants were aware of the impact the list price increases for the Insulin Drugs had on the amount paid by similarly situated TPPs.

27. Similarly, Other Direct Purchaser Plaintiffs and similarly situated Class members, purchase the Insulin Drugs directly from the Manufacturer Defendants. The purchase price the Other Direct Purchaser Plaintiffs and Class members pay is the list price set by the Manufacturer Defendants. Thus, the larger the list price, the larger the amount Other Direct Purchaser Class members are charged. Each of the Defendants were aware of the impact the list price increases for the Insulin Drugs had on an Other Direct Purchaser's payments to the Manufacturer Defendants.

28. Manufacturer Defendants publicly represent that the list prices of the Insulin Drugs are just that, *list* prices—a fair representation of the product's value in the market and a reasonable basis for consumer, TPP, and Other Direct Purchaser payments. So, when they inflate their list prices to arbitrary levels, solely to provide increased rebates and fees in exchange for favorable formulary access, they mislead Plaintiffs and Class members and unfairly force them to pay artificially inflated

prices for their Insulin Drugs. Meanwhile, PBM Defendants publicly represented that they were negotiating with Manufacturer Defendants on behalf of TPPs to keep costs down, but instead participated in a scheme that served to inflate list prices and increase the amounts paid by TPPs.

29. As a result of Defendants' conduct, Plaintiffs and Class members overpaid for the Insulin Drugs when they paid for these medications based on the Manufacturer Defendants' list prices. In this action, Plaintiffs allege a violation of the Racketeer Influenced Corrupt Organization Act ("RICO"), as in this instance, Plaintiffs and Class members purchased Insulin Drugs directly from a RICO-enterprise headed by Defendants. This scheme directly and foreseeably caused, and continues to cause, direct purchasers to overpay for the Insulin Drugs.

30. Plaintiffs additionally assert a Robinson-Patman Act ("RPA") Claim against Defendants because the Manufacturer Defendants paid compensation to the PBM Defendants (who are the agents and/or fiduciaries of TPP Plaintiffs and TPP members of the Class) in the form of inflated and undisclosed rebates, bribes, and phantom "fees" in exchange for favorable formulary placement of the Manufacturer Defendants' drugs. These payments from the Manufacturer Defendants were not for any services rendered in connection with the sale or purchase of the Insulin Drugs, and only served to benefit the PBM Defendants who pocketed these ill-gotten payments which were used by the Manufacturer Defendants as a bribe for formulary

placement of their Insulin Drugs. This scheme directly and foreseeably caused, and continues to cause, Plaintiffs and Class members to overpay for the Insulin Drugs.

II. PARTIES

A. Plaintiffs

31. Plaintiff Local No. 1 Health Fund (as defined above, “Local 1 Health Fund”) is a multi-employer plan whose stated purpose is to provide health benefits to eligible members and their dependents. Local 1 Health Fund is maintained and administered in accordance with and pursuant to the provisions of Section 302(c)(5) of the National Labor Relations Act. Local 1 Health Fund maintains its principal place of business in Downers Grove, Illinois.

32. Plaintiff Plan of Benefits for the Local No. 1 Health Fund and associated plans (as defined above, “Local 1 Health Fund Plan”) is the health benefits plan that the Local 1 Health Fund has sponsored from at least 2008 through the present. The Local 1 Health Fund Plan is based in and administered from Downers Grove, Illinois. The Local 1 Health Fund provides its eligible members and their dependents with healthcare benefits through the Local 1 Health Fund Plan, a self-insured healthcare plan. For the year 2020, approximately 6,000 eligible members and their dependents participated in the Local 1 Health Fund Plan. Local 1 contracts directly with one or more of the Defendants to purchase the Insulin Drugs and will continue to purchase the Insulin Drugs in the future.

33. During the Class Period, Local 1 purchased one or more of the Insulin Drugs, including Basaglar, Fiasp, Novolin, Tresiba, and Toujeo, directly from Express Scripts and/or CVS Caremark via these PBMs' mail order pharmacies. In connection with those direct purchases, Local 1 paid more for Insulin Drugs than it otherwise would have paid had Defendants not engaged in the conduct complained of in this Complaint. Local 1 will continue to purchase the Insulin Drugs in the future. Local 1 has standing and has sustained antitrust injury.

34. Local 837 Health and Welfare Plan (as defined above, "Local 837") provides health benefits for its members. Local 837 is maintained and administered in accordance with and pursuant to the provisions of Section 302(c)(5) of the National Labor Relations Act. Local 837 maintains its principal place of business in Philadelphia, Pennsylvania. Local 837 contracts directly with one or more of the Defendants to purchase the Insulin Drugs and will continue to purchase the Insulin Drugs in the future.

35. During the Class Period, Local 837 purchased one or more of the Insulin Drugs, including Basaglar, Humalog, Humulin, Lantus, Novolog, and Tresiba, directly from OptumRx via their mail order pharmacy. In connection with those direct purchases, Local 837 paid more for Insulin Drugs than it otherwise would have paid had Defendants not engaged in the conduct complained of in this Complaint. Local 837 has standing and has sustained antitrust injury.

36. Plaintiff FWK Holdings, LLC (as defined above, “FWK”) is an Illinois limited liability company with its principal place of business located in Glen Ellyn, Illinois. FWK is the assignee of Frank W. Kerr Co. (“Kerr”) in relation to certain antitrust and RICO claims resulting from Kerr’s purchase of pharmaceutical and over-the-counter products.

37. During the Class Period, Kerr contracted directly with and paid directly one or more Defendants for the purchase of one or more Insulin Drugs, including Apidra, Humalog, Humulin, Lantus, Levemir, Novolog, Novolin, Toujeo, and Tresiba from Sanofi, Novo Nordisk, and Eli Lilly. In connection with those direct purchases, Kerr paid more for the Insulin Drugs than it otherwise would have paid had Defendants not engaged in the conduct alleged in this Complaint. Pursuant to its assignment agreement and addendum, FWK stands in the shoes of Kerr for purposes of pursuing relief in this litigation.

38. Plaintiff Professional Drug Company, Inc. (as defined above, “PDC”) is a Mississippi corporation with its principal place of business located at 186 Bohn Street, Biloxi, Mississippi. PDC contracts directly with one or more of the Defendants to purchase the Insulin Drugs and will continue to purchase the Insulin Drugs in the future.

39. During the Class Period, PDC paid for one or more of the Insulin Drugs, including Lantus and Levemir from Sanofi and Novo Nordisk. In connection with

those direct purchases, PDC paid more for Insulin Drugs than it otherwise would have paid had Defendants not engaged in the conduct complained of in this Complaint.

B. Manufacturer Defendants

40. Defendant Eli Lilly and Company is a corporation organized and existing under the laws of the State of Indiana. Eli Lilly's principal place of business is Lilly Corporate Center, Indianapolis, Indiana 46285. Eli Lilly manufactures Humalog, Humulin, and Basaglar, which are used for the treatment of diabetes. Eli Lilly's revenues from Humalog were \$2.06 billion in 2022 and \$2.45 billion in 2021.

41. Defendant Novo Nordisk Inc. is a Delaware corporation and has its principal place of business at 800 Scudders Mill Road, Plainsboro, New Jersey 08536. Novo Nordisk manufactures Fiasp, Novolog, Levemir, Novolin, and Tresiba, which are used for the treatment of diabetes. Novo Nordisk's net sales of all its insulin products totaled €38.76 billion DKK (or approximately \$5.61 billion) in 2022 and €39.94 billion DKK (or approximately \$5.78 billion) in 2021.

42. Defendant Sanofi-Aventis U.S. LLC is a Delaware limited liability corporation with a principal place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807. Sanofi manufactures Apidra, Lantus, and Toujeo, which are used for the treatment of diabetes. Sanofi's net sales from Lantus were €2.25 billion (approximately \$2.44 billion) in 2022 and €2.49 billion (approximately \$2.7 billion)

in 2021. Sanofi's SEC Form 20-F for the year 2022 notes that "Lantus® is particularly important; it was one of Sanofi's leading products in 2022"⁹

C. PBM Defendants

1. CVS Caremark

43. Defendant CVS Health Corporation ("CVS Health") is a Delaware corporation with its principal place of business at One CVS Drive, Woonsocket, Rhode Island 02895.

44. CVS Health—through its executives and employees, including its CEO, Chief Medical Officer, Executive Vice Presidents, Senior Executives in Trade Finance, Senior Vice Presidents, and Chief Communication Officers—is directly involved in creating and implementing the company policies that inform its PBM services and formulary construction, including with respect to the pricing and kickback scheme.

45. On a regular basis, CVS Health executives and employees communicate with and direct its subsidiaries related to the at-issue PBM services and formulary activities.

46. In each annual report for at least the last decade, CVS Health (or its predecessor) has repeatedly and explicitly stated that CVS Health itself:

- a. designs pharmacy benefit plans that minimize the costs to the client while prioritizing the welfare and safety of the clients' members;

⁹ Sanofi, Annual Report at 9 (Form 20-F) (Feb. 24, 2023).

- b. negotiates with pharmaceutical companies to obtain discounted acquisition costs for many of the products on CVS Health's drug lists, and these negotiated discounts enable CVS Health to offer reduced costs to clients; and
- c. utilizes an independent panel of doctors, pharmacists and other medical experts, referred to as its "Pharmacy and Therapeutics Committee," to select drugs that meet the highest standards of safety and efficacy for inclusion on its drug lists.¹⁰

47. CVS Health publicly represents that it lowers the cost of the Insulin Drugs. For example, in 2016 CVS Health announced a new program to "reduce overall health care spend[ing] in diabetes," stating that CVS Health introduced:

[A] new program available to help the company's pharmacy benefit management (PBM) clients improve the health outcomes of their members, *lower pharmacy costs* [for diabetes medications] through aggressive trend management and decrease medical costs . . . [and that] participating clients could save between \$3,000 to \$5,000 per year for each member who successfully improves control of their diabetes. (emphasis added).¹¹

48. A 2017 CVS Health report stated that "CVS Health pharmacy benefit management (PBM) strategies reduced trend for commercial clients to 1.9 percent per member per year (PMPY) the lowest in five years. Despite manufacturer price

¹⁰ CVS Health Annual Reports (Form 10-K) (2009-2022).

¹¹ *CVS Health Introduces New "Transform Diabetes Care™" Program to Improve Health Outcomes and Lower Overall Health Care Costs*, CVS Health, (Dec. 13, 2016), <https://www.prnewswire.com/news-releases/cvs-health-introduces-new-transform-diabetes-care-program-to-improve-health-outcomes-and-lower-overall-health-care-costs-300377101.html>.

increases of near 10 percent, CVS Health kept drug price growth at a minimal 0.2 percent.”¹²

49. In November 2018, CVS Health acquired Aetna for \$69 billion and became the first combination of a major health insurer, PBM, and mail order, and retail pharmacy chain. As a result, CVS Health controls the health plan/insurer, the PBM, and the pharmacies utilized by approximately 40 million Aetna members in the United States. CVS Health controls the entire drug pricing chain for these 40 million Americans.

50. CVS Health is the immediate or indirect parent of many pharmacy subsidiaries that own pharmacies throughout the country—including CVS Pharmacy, Inc.—that dispensed and received payment for the Insulin Drugs throughout the relevant period. According to CVS Health’s 2022 Form 10-K filed with the U.S. Securities and Exchange Commission, the company “maintains a national network of approximately 66,000 retail pharmacies, consisting of approximately 40,000 chain pharmacies (which include CVS Pharmacy locations) and approximately 26,000 independent pharmacies, in the United States.”¹³

51. Defendant Caremark Rx, LLC is a Delaware limited liability company with its principal place of business located at One CVS Drive, Woonsocket, Rhode

¹² See CVS Health Drug Trend Report (2017), https://s2.q4cdn.com/447711729/files/doc_downloads/company_documents/2017-drug-trend-report.pdf.

¹³ CVS Health, Annual Report (Form 10-K) (Feb. 8, 2023).

Island 02895. During the relevant period, Caremark Rx, LLC provided PBM and mail order pharmacy services that gave rise to and implemented the pricing and kickback scheme as alleged herein to the detriment of Plaintiffs and the Class. Caremark Rx, LLC is a wholly owned subsidiary of CVS Health.

52. Defendant Caremark, LLC is a California limited liability company whose principal place of business is at the same location as CVS Health. Caremark, LLC is a subsidiary of Caremark Rx, LLC.

53. During the relevant period, Caremark, LLC provided PBM and mail order pharmacy services that gave rise to and implemented the pricing and kickback scheme as alleged herein to the detriment of Plaintiffs and the Class.

54. Defendant CaremarkPCS Health, LLC (“CaremarkPCS Health”) is a Delaware limited liability company whose principal place of business is at the same location as CVS Health.

55. CaremarkPCS Health is a subsidiary of CaremarkPCS, LLC, which is a subsidiary of Caremark Rx, LLC.

56. CaremarkPCS Health, doing business as CVS Caremark, provides pharmacy-benefit-management services.

57. During the relevant period, CaremarkPCS Health provided PBM services that gave rise to and implemented the pricing and kickback scheme as alleged herein to the detriment of Plaintiffs and the Class.

58. As a result of numerous interlocking directorships and shared executives, Caremark Rx, LLC, CVS Pharmacy, and CVS Health are directly involved in the conduct of and control of CaremarkPCS Health's and Caremark, LLC's operations, management, and business decisions related to the at-issue formulary construction; Manufacturer Payments; and mail order services—to the ultimate detriment of Plaintiffs and the Class. For example:

- a. During the relevant period, these parents and subsidiaries have had common officers and directors, including:
 - i. Thomas S. Moffatt, Vice President and Secretary of Caremark Rx, LLC, CaremarkPCS Health, and Caremark, LLC, has also served as Vice President, Assistant Secretary, and Senior Legal Counsel at CVS Health and the Vice President, Secretary and Senior Legal Counsel of CVS Pharmacy;
 - ii. Melanie K. Luker, Assistant Secretary of Caremark Rx, LLC, CaremarkPCS Health, and Caremark, LLC, has also served as Manager of Corporate Services at CVS Health;
 - iii. Carol A. Denale, Senior Vice President and Treasurer of Caremark Rx, LLC, has also served as Senior Vice President, Treasurer, and Chief Risk Officer at CVS Health Corporation;
 - iv. John M. Conroy has been Vice President of Finance at CVS Health since 2011, and has also served as President and Treasurer of Caremark, LLC and CaremarkPCS Health in 2019; and
 - v. Sheelagh Beaulieu has been the Senior Director of Income Tax at CVS Health while also acting as the Assistant Treasurer at CaremarkPCS Health and Caremark, LLC.
- b. CVS Health owns all the stock of CVS Pharmacy, which owns all the stock of Caremark Rx, LLC, which owns all

the stock of Caremark LLC. CVS Health directly or indirectly owns CaremarkPCS Health in its entirety.

- c. CVS Health, as a corporate unit, does not operate as separate entities. Rather, its public filings, documents and statements present its subsidiaries—including CVS Pharmacy, Caremark Rx, LLC, Caremark, LLC, and CaremarkPCS Health—as divisions or departments of one unified “diversified health services company” that “works together across our disciplines” to “create unmatched human connections to transform the health care experience.” The day-to-day operations of this corporate unit reflect these public statements. These entities constitute a single business enterprise and should be treated as such as to all legal obligations discussed in this Complaint.¹⁴
- d. All executives of CaremarkPCS Health, Caremark, LLC, Caremark Rx, LLC, and CVS Pharmacy ultimately report to the executives at CVS Health, including its President and CEO.
- e. As stated above, CVS Health’s CEO, Chief Medical Officer, Executive Vice Presidents, Senior Executives in Trade Finance, Senior Vice Presidents and Chief Communication Officers are directly involved in the policies and business decisions by Caremark, LLC and CaremarkPCS Health that give rise to Plaintiffs’ claims.

59. Defendant Zinc Health Services, LLC (as defined above, “Zinc”) is a rebate aggregator for Caremark’s PBM business. CVS Health through Zinc negotiates rebates with drug manufacturers on behalf of Caremark’s and other third

¹⁴ CVS Health, Annual Reports (Form 10-K) (2009-2019); *Our Purpose*, CVS Health, <https://cvshealth.com/about-cvs-health/our-purpose> (last visited Sept. 30, 2024); *See Our Services*, CVS Health, <https://www.cvshealth.com/services.html> (last visited Oct. 3, 2024).

parties' commercial clients. Zinc serves as an agent or designee on behalf CVS Caremark.

60. Defendants CVS Health, Caremark Rx LLC, Caremark, LLC, CaremarkPCS Health, and Zinc, including all predecessor and successor entities, are referred to collectively as "CVS Caremark."

61. CVS Caremark is named as a Defendant in its capacities as a PBM and mail order pharmacy.

62. In its capacities as a PBM and mail order pharmacy, CVS Caremark coordinates with each of the Manufacturer Defendants regarding the price of and rebates and fees paid in conjunction with the Insulin Drugs, as well as for the placement of the Manufacturer Defendants' diabetes medications on CVS Caremark's formularies.

63. CVS Caremark has the largest PBM market share based on total prescription claims managed.

64. At all relevant times, and contrary to its express representations, CVS Caremark knowingly insisted that its TPP clients use the artificially inflated list prices as the basis for their payment of the Insulin Drugs.

65. At all relevant times, CVS Caremark concealed its critical role in the generation of those artificially inflated list prices.

66. At all relevant times, CVS Caremark offered PBM services nationwide and maintained standard formularies that were used by TPPs and the plaintiff plans nationwide. Those formularies included diabetes medications, including the Insulin Drugs.

67. During the relevant period, CVS Caremark made representations to TPPs through proposals to provide PBM services in response to requests for proposals. In doing so, CVS Caremark reinforced the artificially inflated list prices for the Insulin Drugs.

68. At all relevant times, CVS Caremark had express agreements with Novo Nordisk, Sanofi, and Eli Lilly related to rebates and other payments paid by the Manufacturer Defendants to CVS Caremark.

2. Express Scripts

69. Defendant Evernorth Health, Inc. (“Evernorth”), formerly known as Express Scripts Holding Company, Inc., is a Delaware corporation with its principal place of business at One Express Way, St. Louis, Missouri 63121.¹⁵

70. Evernorth, through its executives and employees, including its CEO and Vice Presidents, is directly involved in shaping the company policies that inform

¹⁵ Until 2021, Evernorth Health, Inc. operated under the name Express Scripts Holding Company. In this Complaint, “Evernorth” refers collectively to Evernorth Health, Inc. and Express Scripts Holding Company.

its PBM services and formulary construction, including with respect to the pricing and kickback scheme for the Insulin Drugs.

71. On a regular basis, Evernorth executives and employees communicate with and direct Evernorth's subsidiaries related to the at-issue PBM services and formulary activities.

72. In 2018, Cigna acquired Express Scripts in a \$67 billion deal, and in 2020, Cigna rebranded its health services portfolio as Evernorth. The merger consolidated their businesses as a major health insurer, PBM, and mail order pharmacy. As a result, the Evernorth corporate family controls the health plan/insurer, the PBM, and the mail order pharmacies utilized by approximately 15 million Cigna members in the United States. Evernorth controls the entire drug pricing chain for these 15 million Americans.

73. Evernorth's annual reports over the past several years have repeatedly and explicitly:

- a. Acknowledged that it is directly involved in the company's PBM services, stating “[Evernorth is] the largest independent [PBM] company in the United States.”
- b. Stated that Evernorth controls costs, including for example, that it: “identif[ies] products and offer[s] solutions that focus on improving patient outcomes and assist in controlling costs; evaluat[es] drugs for efficacy, value and price to assist clients in selecting a cost-effective formulary; [and] offer[s] cost-effective home delivery pharmacy and

specialty services that result in cost savings for plan sponsors and better care for members.”¹⁶

74. Even after the merger with Cigna, Evernorth “operates various group purchasing organizations that negotiate pricing for the purchase of pharmaceuticals and formulary rebates with pharmaceutical manufacturers on behalf of their participants” and operates the company’s Pharmacy Rebate Program while its subsidiary Express Scripts provides “formulary management services” that ostensibly “assist customers and physicians in choosing clinically-appropriate, cost-effective drugs and prioritize access, safety and affordability.” In 2021, Evernorth reported adjusted revenues of \$131.9 billion (representing 75.8% of Cigna Corporation’s revenues), up from \$116.1 billion in 2020.¹⁷

75. Defendant Express Scripts, Inc. is a Delaware corporation and is a wholly owned subsidiary of Defendant Evernorth. Express Scripts, Inc.’s principal place of business is at the same location as Evernorth.

76. Express Scripts, Inc. is the immediate or indirect parent of PBM subsidiaries that operates throughout the country and engaged in the conduct that gave rise to this action.¹⁸

¹⁶ Express Scripts Holding Co., Annual Reports (2009-2019); Cigna Corp., Annual Reports (Form 10-K) (Feb. 25, 2021 & Feb. 24, 2022).

¹⁷ Cigna Annual Report (Form 10-K) (FYE Dec. 31, 2021).

¹⁸ Express Scripts Annual Report (Form 10-K, Exhibit 21.1) (FYE Dec. 31, 2018).

77. During the relevant period, Express Scripts, Inc. was directly involved in PBM services and mail order pharmacy services that gave rise to and implemented the pricing and kickback scheme as alleged herein to the detriment of Plaintiffs and the Class.

78. Defendant Express Scripts Administrators, LLC, doing business as Express Scripts and formerly known as Medco Health, LLC, is a Delaware limited liability company and is a wholly owned subsidiary of Evernorth. Its principal place of business is at the same location as Evernorth.

79. During the relevant period, Express Scripts Administrators, LLC provided PBM and mail order pharmacy services that gave rise to and implemented the pricing and kickback scheme as alleged herein to the detriment of Plaintiffs and the Class.

80. Defendant Medco Health Solutions, Inc. (“Medco”) is a Delaware Corporation whose principal place of business is at the same location as Evernorth.

81. In 2012, Express Scripts acquired Medco for \$29 billion.

82. Prior to the merger, Medco provided PBM and mail order pharmacy services that gave rise to and implemented the pricing and kickback scheme as alleged herein to the detriment of Plaintiffs and the Class.

83. Following the merger, all of Medco’s PBM and mail order pharmacy functions were combined into Express Scripts. The combined company (Medco and

Express Scripts) continued under the name Express Scripts, with all of Medco's TPP customers becoming Express Scripts' customers. The combined company covered over 155 million lives at the time of the merger.

84. At the time of the merger, on December 6, 2011, in his testimony before the Senate Judiciary Committee, David Snow, then-CEO of Medco, publicly represented that "the merger of Medco and Express Scripts will result in immediate savings to our clients and, ultimately, to consumers. This is because our combined entity will achieve even greater purchasing volume discounts from drug manufacturers and other suppliers."¹⁹

85. At the same time, the then-CEO of Express Scripts, George Paz, provided written testimony to the Senate Judiciary Committee's Subcommittee on Antitrust, Competition Policy and Consumer Rights, stating: "A combined Express Scripts and Medco will be well-positioned to protect American families from the rising cost of prescription medicines." First on Mr. Paz's list of "benefits of this merger" was "[g]enerating greater cost savings for patients and plan sponsors."²⁰

¹⁹ Testimony of David B. Snow, Jr. at 11, Before the S. Comm. on the Judiciary; Subcomm. on Antitrust, Competition Policy & Consumer Rights (Dec. 6, 2011), <https://www.judiciary.senate.gov/imo/media/doc/11-12-6SnowTestimony.pdf>.

²⁰ Testimony of George Paz. at 8, Before the S. Comm. on the Judiciary; Subcomm. on Antitrust, Competition Policy & Consumer Rights (Dec. 6, 2011), <https://www.judiciary.senate.gov/imo/media/doc/11-12-6PazTestimony.pdf>.

86. Defendant ESI Mail Pharmacy Service, Inc. is a Delaware corporation with its principal place of business located at 1 Express Way, St. Louis, Missouri 63121. ESI Mail Pharmacy Services, Inc. is a wholly owned subsidiary of Evernorth. During the Class Period, ESI Mail Pharmacy Service, Inc., provided mail order pharmacy services that gave rise to the pricing and kickback scheme as alleged herein to the detriment of Plaintiffs and the Class.

87. Defendant Express Scripts Pharmacy, Inc. is a Delaware corporation with its principal place of business located at 1 Express Way, St. Louis, Missouri 63121. Express Scripts Pharmacy, Inc. is a wholly owned subsidiary of Evernorth. During the relevant period, Express Scripts Pharmacy, Inc., provided mail order pharmacy services that gave rise to the pricing and kickback scheme as alleged herein to the detriment of Plaintiffs and the Class.

88. As a result of numerous interlocking directorships and shared executives, Evernorth and Express Scripts, Inc. control Express Scripts Administrators, LLC's, ESI Mail Pharmacy Service, Inc.'s, Medco Health Solutions, Inc.'s, and Express Scripts Pharmacy, Inc.'s operations, management, and business decisions related to the at-issue formulary construction, negotiations, and mail order pharmacy services to the ultimate detriment of Plaintiffs and the Class. For example:

- a. During the relevant period, these entities have had common officers and directors:

- i. officers and/or directors shared between Express Scripts, Inc. and Evernorth include Bradley Phillips, Chief Financial Officer; David Queller, President; Jill Stadelman, Managing Counsel; Dave Anderson, VP of Strategy; Matt Perlberg, President of Pharmacy Businesses; Bill Spehr, SVP of Sales; and Scott Lambert, Treasury Manager Director;
 - ii. executives shared between Express Scripts Administrators, LLC and Evernorth include Bradley Phillips, Chief Financial Officer; and Priscilla Duncan, Associate Senior Counsel;
 - iii. officers and/or directors shared between ESI Mail Pharmacy Service, Inc. and Evernorth include Bradley Phillips, Chief Financial Officer; Priscilla Duncan, Associate Senior Counsel; and Joanne Hart, Treasury Director; and
 - iv. officers and/or directors shared between Express Scripts Pharmacy, Inc. and Evernorth include Bradley Phillips, Chief Financial Officer; Jill Stadelman, Managing Counsel; Scott Lambert, Treasury Manager Director; and Joanne Hart, Treasury Director.
- b. Evernorth directly or indirectly owns all the stock of Express Scripts Administrators, LLC, Medco Health Solutions, Inc., ESI Mail Pharmacy Service, Inc., Express Scripts Pharmacy, Inc., and Express Scripts, Inc.²¹
- c. The Evernorth corporate family does not operate as separate entities. Evernorth's public filings, documents, and statements present its subsidiaries, including Express Scripts Administrators, LLC, ESI Mail Pharmacy Service, Inc., Express Scripts Pharmacy, Inc. and Express Scripts, Inc., as divisions or departments of a single company that "leverag[es] its" entire suite of capabilities. Cross-enterprise leverage brings teams from across the enterprise together in a quick, efficient and organized manner to move from ideation to solution creation to meet client's

²¹ Express Scripts Annual Report (Form 10-K, Exhibit 21) (FYE Dec. 31, 2018).

evolving needs.”²² The day-to-day operations of this corporate family reflect these public statements. All of these entities comprise a single business enterprise and should be treated as such as to all legal obligations detailed in this Complaint.

- d. All of the executives of Express Scripts Administrators, LLC, ESI Mail Pharmacy Service, Inc., Express Scripts Pharmacy, Inc., and Express Scripts, Inc. ultimately report to the executives, including the CEO, of Evernorth.
- e. As stated above, Evernorth’s CEO and other executives and officers are directly involved in the policies and business decisions of Express Scripts Administrators, LLC, ESI Mail Pharmacy Service, Inc., Medco Health Solutions, Inc., Express Scripts Pharmacy, Inc., and Express Scripts, Inc. that gave rise to Plaintiffs’ claims in this Complaint.

89. Defendant Ascent Health Services LLC (as defined above, “Ascent”) is a rebate aggregator for Express Script’s PBM business. Express Scripts through Ascent negotiates rebates with drug manufacturers on behalf of Express Scripts and other third parties’ commercial clients. Ascent serves as an agent or designee on behalf Express Scripts.

90. Defendants Evernorth, Express Scripts, Inc., Express Scripts Administrators, LLC, Medco Health Solutions, Inc., ESI Mail Pharmacy Services, Inc., Express Scripts Pharmacy, Inc., and Ascent, including all predecessor and successor entities, are referred to collectively as “Express Scripts.”

²² Cigna Group Annual Report (Form 10-K) (FYE Dec. 31, 2023).

91. Express Scripts is named as a Defendant in its capacities as a PBM and mail order pharmacy.

92. In its capacities as a PBM and mail order pharmacy, Express Scripts coordinates with each of the Manufacturer Defendants regarding the price of the Insulin Drugs, as well as for the placement of these Manufacturer Defendants' diabetes medications on Express Scripts' formularies.

93. Prior to merging with Cigna in 2018, Express Scripts was the largest independent PBM in the United States.²³ During the timeframe relevant to this Complaint, Express Scripts controlled 30% of the PBM market in the United States. Express Scripts has only grown larger since the Cigna merger.

94. In 2017, annual revenue for Express Scripts exceeded \$100 billion.²⁴

95. As of December 31, 2017, more than 68,000 retail pharmacies, representing over 98% of all retail pharmacies in the nation, participated in one or more of Express Scripts' networks.²⁵

96. At all relevant times, and contrary to its express representations, Express Scripts knowingly insisted that its TPP clients use the artificially inflated list prices as the basis for purchases of the Insulin Drugs.

²³ Express Scripts Holding Co., Annual Report (Form 10-K) (FYE Dec. 31, 2017).

²⁴ *Id.*

²⁵ *Id.*

97. At all times relevant hereto, Express Scripts concealed its critical role in the generation of those artificially inflated list prices.

98. At all relevant times, Express Scripts offered PBM services nationwide and maintained standard formularies that are used by TPPs nationwide. Those formularies included diabetes medications, including the Insulin Drugs.

99. During certain years when some of the largest at-issue price increases occurred, including in 2013 and 2014, Express Scripts worked directly with OptumRx to negotiate rebates and other payments on behalf of OptumRx and its clients in exchange for preferred formulary placement. For example, in a February 2014 email released by the U.S. Senate in conjunction with an investigation into insulin pricing, Eli Lilly describes a “Russian nested doll situation” in which Express Scripts was negotiating rebates on behalf of OptumRx related to the Insulin Drugs for Cigna (who later would become part of Express Scripts).²⁶

100. At all relevant times, Express Scripts had express agreements with each of the Manufacturer Defendants related to rebates and other payments paid by the Manufacturer Defendants to Express Scripts.

²⁶ Staff of S. Comm. on Fin, 116th Cong., Rep. on Insulin; Letter from Joseph B. Kelley, Eli Lilly Vice President, Glob. Gov’t Affairs, to Charles E. Grassley & Ron Wyden at 2, S. Fin. Comm. (Mar. 8, 2019), https://www.finance.senate.gov/imo/media/doc/Eli%20Lilly_Redacted%20v1.pdf.

3. OptumRx

101. Defendant UnitedHealth Group, Inc. is a corporation organized under the laws of Delaware with its principal place of business at 9900 Bren Road East, Minnetonka, Minnesota, 55343.

102. UnitedHealth Group, Inc. is a diversified managed healthcare company. Its total revenues in 2022 exceeded \$324 million. In 2021, its revenues exceeded \$287 million. Since 2020, its revenues have increased by more than \$30 million per year. The company currently is ranked fifth on the Fortune 500 list.²⁷

103. UnitedHealth Group, Inc. offers a spectrum of products and services including health insurance plans, PBM services, and mail order pharmacy services through its wholly owned subsidiaries. Over one-third of UnitedHealth Group's total revenue is attributable to OptumRx, which operates a network of more than 67,000 pharmacies.

104. UnitedHealth Group, through its executives and employees, is directly involved in the company policies that shape its PBM and mail order pharmacy services, and formulary construction, including with respect to the pricing and kickback scheme for the Insulin Drugs. For example, UnitedHealth Group executives' structure, analyze, and direct the company's overarching policies,

²⁷ UnitedHealth Group, Inc. Annual Report (Form 10-K) (FYE Dec. 31, 2022).

including as to PBM services, as a means of maximizing profitability across the corporate family.

105. UnitedHealth Group's 2020 Sustainability Report states that:

Its OptumRx business "works directly with pharmaceutical manufacturers to secure discounts that lower the overall cost of medications and create[s] tailored formularies – or drug lists – to ensure people get the right medications," and it "then negotiate[s] with pharmacies to lower costs at the point of sale."²⁸

106. In addition to being a PBM and a mail order pharmacy, UnitedHealth Group owns and controls a major health insurance company, UnitedHealthcare. As a result, UnitedHealth Group controls the health plan/insurer, the PBM, and the mail order pharmacies utilized by more than 26 million UnitedHealthcare members in the United States. UnitedHealth Group controls the entire drug pricing chain for these 26 million Americans.

107. UnitedHealth Group states in its annual reports that UnitedHealth Group "uses Optum's capabilities to help coordinate and provide patient care, improve affordability of medical care, analyze cost trends, manage pharmacy care services, work with care providers more effectively and create a simpler and more satisfying consumer . . . experience."²⁹ Its most recent annual report states plainly that it is "involved in establishing the prices charged by retail pharmacies,

²⁸ *Sustainability Rep.*, UnitedHealth Grp. at 51 (2021), https://www.unitedhealthgroup.com/content/dam/UHG/PDF/sustainability/final/2020_SustainabilityReport.pdf.

²⁹ UnitedHealth Grp., Inc., Annual Report (Form 10-K) (Feb. 24, 2023).

determining which drugs will be included in formulary listings and selecting which retail pharmacies will be included in the network offered to plan sponsors' members[.]”³⁰

108. As of December 31, 2022 and 2021, UnitedHealth Group's “total pharmaceutical manufacturer rebates receivable included in other receivables in the Consolidated Balance Sheets amounted to \$8.2 billion and \$7.2 billion, respectively,”³¹ up even from \$6.3 billion in 2020.³²

109. Defendant Optum, Inc. is a Delaware corporation with its principal place of business located in Eden Prairie, Minnesota. Optum, Inc. is a health services company managing subsidiaries, including Defendant OptumRx, Inc., that administer PBM and mail order pharmacy services.³³

110. Optum, Inc. is directly involved, through its executives and employees, in the company policies that inform its PBM services and formulary construction, including with respect to the pricing and kickback scheme for the Insulin Drugs.

111. For example, according to an Optum, Inc. press releases, Optum, Inc. is “UnitedHealth Group's \$27 billion information and technology-enabled health services business platform serving the broad health care marketplace, including care

³⁰ *Id.*

³¹ *Id.*

³² UnitedHealth Grp., Inc., Annual Report (Form 10-K) (Feb. 15, 2022).

³³ UnitedHealth Group Annual Report (Form 10-K) (FYE Dec. 31, 2022).

providers, plan sponsors, payers, life sciences companies and consumers.”³⁴ In this role, Optum, Inc. is directly responsible for the “business units—OptumInsight, OptumHealth and OptumRx,”³⁵ and the CEOs of these companies report directly to Optum, Inc. regarding their policies, including those that inform the at-issue formulary construction and mail order activities.

112. Defendant OptumRx, Inc. is a California corporation with its principal place of business at 2300 Main Street, Irvine, California, 92614.

113. OptumRx, Inc. operates as a subsidiary of OptumRx Holdings, LLC, which, in turn, operates as a subsidiary of Defendant Optum, Inc.

114. OptumRx, Inc. is, and since 2001 has been, registered to do business in New Jersey.

115. During the relevant period, OptumRx, Inc. provided the PBM and mail order pharmacy services that gave rise to and implemented the pricing and kickback scheme for the Insulin Drugs as alleged herein to the detriment of Plaintiffs and the Class.

116. Defendant OptumInsight, Inc. (“OptumInsight”) is a Delaware corporation with its principal place of business located in Eden Prairie, Minnesota.

³⁴ UnitedHealth Grp., Inc., (Form 8-K) (July 6, 2011) at Ex. 99.1, Press Release, Larry Renfro Named CEO of Optum, <https://www.sec.gov/Archives/edgar/data/731766/000119312511182325/dex991.htm>.

³⁵ *Id.*

117. OptumInsight is an integral part of the pricing scheme and, during the relevant period, coordinated directly with the Manufacturer Defendants in furtherance of the pricing scheme. OptumInsight analyzed data and other information from the Manufacturer Defendants to advise the other Defendants about the profitability of the pricing and kickback scheme to the benefit of all Defendants.

118. Defendant Emisar Pharma Services LLC (as defined above, “Emisar”) is a Delaware limited liability company with its principal place of business in Ireland. In 2021, OptumRx established Emisar as a rebate aggregator for OptumRx’s PBM business. Emisar is a wholly owned indirect subsidiary of UnitedHealth Group Inc.

119. As a result of numerous interlocking directorships and shared executives, UnitedHealth Group, OptumRx Holdings, LLC, and Optum, Inc. are directly involved in the conduct of and control OptumInsight’s and OptumRx, Inc.’s operations, management, and business decisions related to the at-issue formulary construction, negotiations, and mail order pharmacy services to the ultimate detriment of Plaintiffs and the Class. For example:

- a. These entities have common officers and directors, including:
 - i. Andrew Witty is the CEO and on the Board of Directors for UnitedHealth Group and previously served as CEO of Optum, Inc.;
 - ii. Dan Schumacher is Chief Strategy and Growth Officer at UnitedHealth Group and is CEO of

OptumInsight, having previously served as president of Optum, Inc.;

- iii. Dirk McMahon is President and COO of UnitedHealth Group. He served as President and COO of Optum from 2017 to 2019 and as CEO of OptumRx from 2011 to 2014.
 - iv. John Rex has been an Executive Vice President and CFO of UnitedHealth Group since 2016 and previously served in the same roles at Optum beginning in 2012.
 - v. Terry Clark is a senior vice president and has served as chief marketing officer at UnitedHealth Group since 2014 while also serving chief marketing and customer officer for Optum.
 - vi. Tom Roos has served since 2015 as SVP and chief accounting officer for UnitedHealth Group and Optum, Inc.
 - vii. Heather Cianfrocco joined UnitedHealth Group in 2008 and has held numerous leadership positions within the company while today she is CEO of OptumRx.
 - viii. Peter Gill has served as SVP and Treasurer for UnitedHealth Group and also as Treasurer at OptumRx, Inc.
 - ix. John Santelli led Optum Technology, the leading technology division of Optum, Inc. serving the broad customer base of Optum and UnitedHealthcare and also served as UnitedHealth Group's chief information officer.
 - x. Eric Murphy, now retired, was the Chief Growth and Commercial Officer for Optum, Inc. and also was CEO of OptumInsight beginning in 2017.
- b. UnitedHealth Group directly or indirectly owns all the stock of Optum, Inc., OptumRx, Inc., and OptumInsight;
 - c. The UnitedHealth Group corporate family does not operate as separate entities. The public filings, documents,

and statements of UnitedHealth Group present its subsidiaries, including Optum, Inc., OptumRx, Inc., and OptumInsight as divisions, departments, or “segments” of a single company that is “a diversified family of businesses” and that “leverages core competencies” to “help[] people live healthier lives and helping to make the health system work better for everyone.” The day-to-day operations of this corporate family reflect these public statements. These entities are a single business enterprise and should be treated as such as to all legal obligations detailed in this Complaint.³⁶

- d. All executives of Optum, Inc., OptumRx, Inc., and OptumInsight ultimately report to the executives, including the CEO, of UnitedHealth Group.
- e. As stated above, UnitedHealth Group’s executives and officers are directly involved in the policies and business decisions of Optum, Inc., OptumRx, Inc., and OptumInsight that gave rise to Plaintiffs’ and Class members’ claims.

120. Defendant Emisar Pharma Services LLC (“Emisar”) is a rebate aggregator for Optum’s PBM business. Optum through Emisar negotiates rebates with drug manufacturers on behalf of Optum and other third parties’ commercial clients. Emisar serves as an agent or designee on behalf of Optum.

121. Defendants UnitedHealth Group, Inc., Optum, Inc., OptumRx, Inc., OptumInsight, and Emisar, including all predecessor and successor entities, are referred to collectively as “OptumRx.”

122. OptumRx is named as a Defendant in its capacities as a PBM and mail order pharmacy.

³⁶ UnitedHealth Grp., Inc., Quarterly Report (Form 10-Q) (May 8, 2017).

123. In its capacities as a PBM and mail order pharmacy, OptumRx coordinates with each of the Manufacturer Defendants regarding the price of Insulin Drugs, as well as for the placement of Manufacturer Defendants' diabetes medications on OptumRx's drug formularies.

124. "In 2022, OptumRx managed \$124 billion in pharmaceutical spending, including \$52 billion in specialty pharmaceutical spending."³⁷

125. For the years 2018 through 2022, OptumRx managed \$91 billion, \$96 billion, \$105 billion, \$112 billion, and \$124 billion in pharmaceutical spending, respectively.³⁸

126. In 2019, OptumRx's revenue (excluding UnitedHealthcare) totaled \$74 billion. By 2022, it had risen to over \$99 billion.³⁹

127. At all relevant times, and contrary to its express representations, OptumRx knowingly insisted that its TPP clients use the artificially inflated list prices as the basis for purchases of the Insulin Drugs.

128. At all relevant times, OptumRx concealed its critical role in the generation of those artificially inflated list prices.

³⁷ UnitedHealth Grp., Inc., Annual Report (Form 10-K) (Feb. 24, 2023).

³⁸ UnitedHealth Grp., Inc., Annual Reports (Form 10-K) (2019-2023).

³⁹ *Id.*

129. At all relevant times, OptumRx offered PBM services nationwide and maintained standard formularies that are used by TPPs nationwide. Those formularies included diabetes medications, including the Insulin Drugs.

130. At all relevant times, OptumRx had express agreements with each of the Manufacturer Defendants related to the rebates and other payments paid by the Manufacturer Defendants to OptumRx.

131. As set forth above, CVS Caremark, Express Scripts, and OptumRx are referred to collectively as the “PBM Defendants.”

D. Rebate Aggregator Defendants

132. Zinc is a Delaware limited liability company with its principal place of business at One CVS Drive, Woonsocket, Rhode Island. In 2020, CVS Health Corporation established Zinc as a rebate aggregator for Caremark’s PBM business. CVS Health Corporation through Zinc negotiates rebates with drug manufacturers on behalf of Caremark’s and other third parties’ commercial clients.

133. Zinc serves as an agent or designee on behalf CVS Caremark. Zinc negotiates rebates with drug manufacturers as the agent for and on behalf of CVS Health’s PBM business and is designated by CVS Health to receive for the benefit of CVS Health, rebates, discounts and other payments that are often disguised as “fees” and are paid by drug manufacturers, including the Manufacturer Defendants. These rebates, discounts, and purported “fees” are undisclosed to Plaintiffs and Class

members and are received by Zinc for and on behalf of CVS Health or its wholly owned and controlled subsidiaries.

134. Ascent is a Delaware limited liability company with its principal place of business at Mühlentalstrasse 36, 8200 Schaffhausen, Switzerland. In 2019, ESI established Ascent as a group purchasing organization for ESI's PBM business. Ascent negotiates rebates with drug manufacturers on behalf of ESI's and other third parties' commercial clients.

135. Ascent serves as an agent or designee on behalf ESI. Ascent negotiates rebates with drug manufacturers as the agent for and on behalf of ESI's PBM business and is designated by ESI to receive for the benefit of ESI, rebates, discounts and other payments that are often disguised as "fees" and are paid by drug manufacturers, including the Manufacturer Defendants. These rebates, discounts, and purported "fees" are undisclosed to the plaintiffs and are received by Ascent for and on behalf of ESI or its wholly owned and controlled subsidiaries.

136. Emisar is a Delaware limited liability company with its principal place of business in Ireland. In 2021, Optum established Emisar as a rebate aggregator for Optum's PBM business. Emisar is a wholly owned indirect subsidiary of UnitedHealth Group Inc. Emisar negotiates rebates with drug manufacturers on behalf of Optum's commercial clients.

137. Emisar serves as an agent or designee on behalf Optum. Emisar negotiates rebates with drug manufacturers as the agent for and on behalf of Optum's PBM business and is designated by Optum to receive for the benefit of Optum, rebates, discounts and other payments that are often disguised as "fees" and are paid by drug manufacturers, including the Manufacturer Defendants. These rebates, discounts, and purported "fees" are undisclosed to Plaintiffs and Class members and are received by Emisar for and on behalf of Optum or its wholly owned and controlled subsidiaries.

138. Zinc, Ascent and Emisar each acted as the agent for, on behalf of and at the direction of CVS Caremark, Express Scripts and Optum Rx respectively. Further, Zinc, Ascent, and Emisar consented to act for and on behalf of CVS Caremark, Express Scripts and Optum Rx. Each of those PBM Defendants controlled and directed the acts of its own Rebate Aggregator agent in negotiating prices, rebates, discounts and formulary placement with the Manufacturer Defendants.

139. Each Rebate Aggregator Defendant acted with actual and apparent authority of its separate, respective PBM Defendant and each reasonably believed that it was acting in accord with the manifestations of the PBM Defendant that it so act. The PBM Defendants by making formulary placements in response to the rebates, bribes and payments made by the Manufacturer Defendants to each PBM

Defendants' respective Rebate Aggregator ratified the acts of the Rebate Aggregators Defendants. Such acts were undertaken by each Rebate Aggregator Defendant with the actual authority of its respective PBM Defendant.

III. JURISDICTION AND VENUE

140. The Court has subject matter jurisdiction over Plaintiffs' RICO claims pursuant to 28 U.S.C. § 1331 and 18 U.S.C. § 1964(c), because this action alleges violations of the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. § 1962.

141. This Court has subject matter jurisdiction over Plaintiffs' Section 2(c) Robinson-Patman Act claims pursuant to 28 U.S.C. §§ 1331 and 1337, because Plaintiffs' claims arise under federal antitrust law.

142. This Court also has subject matter jurisdiction pursuant to 28 U.S.C. § 1332(d), which provides federal district courts with original jurisdiction over class action cases in which the matter in controversy exceeds the sum or value of \$5,000,000, exclusive of interests and costs, and at least one member of the class of plaintiffs is a citizen of a state different from any defendant.

143. During the Class Period, the Manufacturer Defendants sold, shipped, and paid kickbacks in connection with the Insulin Drugs, the PBM Defendants received kickbacks in connection with such sales, and the PBM Defendants sold and shipped the Insulin Drugs via their mail order pharmacies, in a continuous and

uninterrupted flow of interstate commerce which included sales of the Insulin Drugs in this District and throughout the United States and kickbacks from the proceeds of such sales. Defendants' conduct had a direct, substantial, and reasonably foreseeable effect on interstate commerce in the United States, including in this District.

144. This Court has personal jurisdiction over each Defendant because, inter alia: (a) certain Defendants maintain their principal places of business in this District; (b) Defendants transacted business throughout the United States, including in this District; (c) Defendants participated in the purchase, sale, and distribution of the Insulin Drugs throughout the United States, including in this District; (d) Defendants had and maintained substantial contacts with the United States, including in this District; (e) Defendants were members of unlawful enterprises designed to artificially inflate the prices for the Insulin Drugs by demanding and receiving substantial kickbacks; and/or (f) those enterprises and kickbacks were directed at and had the intended effect of causing injury to persons residing in, located in, or doing business throughout the United States, including in this District.

145. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1331(b) and (c), because each Defendant transacts business in, is found in, and/or has agents in the District of New Jersey, and because some of the actions giving rise to this Complaint took place within this district.

IV. DRUG PRICING IN THE UNITED STATES

A. Entities Involved in Drug Pricing

146. The prescription drug industry consists of a network of entities, including pharmaceutical companies, wholesalers, pharmacies, TPPs (institutional insurers, self-insured employers, and health and welfare plans), PBMs, and patient-consumers.

147. ***Distribution Chain.*** Generally speaking, for retail pharmacy channels, branded prescription drugs are distributed from manufacturer to wholesaler, wholesaler to retail pharmacy, and retailer to patient. For mail order pharmacies, like those owned by the largest PBM Defendants, branded prescription drugs are distributed from the manufacturer to the mail order pharmacies.

148. ***Pharmaceutical Companies.*** Pharmaceutical companies (also known as drug companies or drug manufacturers) own the rights to manufacture and market drugs. This remains true even if these companies contract out the actual production of their drugs. Pharmaceutical companies typically own or contract with facilities that manufacture drugs and then sell their products to wholesalers. Critically, pharmaceutical companies set the prices of their drugs and then those prices are used to calculate payments consumers and TPPs pay for and/or make at the pharmacy at the point of sale. Manufacturer Defendants here are pharmaceutical companies.

149. ***Wholesalers.*** After production, Manufacturer Defendants send their drugs to FDA-registered drug wholesalers for further distribution. Wholesalers purchase inventory and sell pharmaceutical products to a variety of providers, including retail pharmacy outlets, hospitals, and clinics. The price paid by the wholesalers to purchase Insulin Drugs is set by the Manufacturer Defendants and tied, or tethered, to the list price.

150. The Manufacturer Defendants typically send wholesalers notifications regarding new purchase prices for insulin via the U.S. mail, electronic mail, or interstate wires. Payments for goods and services may be sent through the U.S. banking system by wire transfer, check, or other electronic funds transfers.

151. ***Retail Pharmacies.*** Retail pharmacies purchase drugs from wholesalers or directly from a manufacturer. They then sell these drugs to consumers. When a retail pharmacy (a pharmacy with a physical location) sells a drug to a consumer, it looks up whether or not that consumer holds health insurance and then charges the consumer a price depending on his or her insurance status. Consumers with insurance are usually only responsible for paying a portion of the drug's cost (the "copay"), with the health plan picking up the remainder of the bill. Payments tendered for patients' prescriptions are sent through the U.S. banking system by wire transfer, check, credit/debit card, other electronic funds transfers, or cash.

152. ***Health Benefit Providers.*** Health benefit providers (or TPPs) include institutional insurers, self-insured employers, and health and welfare plans. These plans submit payments on behalf of insured individuals to healthcare providers for services rendered to those individuals. Health insurers also cover a portion of their beneficiaries' drugs costs, submitting payments to pharmacies, including to PBM Defendants' mail order pharmacies, on behalf of their members. The term TPP or "health insurers" includes public and private entities, the latter of which includes self-insured businesses, insurance companies, union-run health plans, and private plans that sponsor Medicaid and Medicare drug benefits.

153. Self-insured health benefit providers—like TPP Plaintiffs and TPP Class members—bear the risk and cost of their members' purchases. Additionally, TPPs pay PBMs directly for drug purchases from PBM mail order pharmacies.

154. ***Pharmacy Benefit Managers.*** PBMs are hired by and act as agents and/or fiduciaries for TPPs to perform some or all of these tasks: (a) administer the terms of the prescription drugs benefits the health benefit provider is obligated to provide under the applicable contracts of insurance and/or applicable statutory/regulatory schemes; (b) pay on behalf of the applicable health benefit provider the amount owed to pharmacies by those health benefit providers for prescription medications dispensed to individuals insured or otherwise covered by the applicable health benefit provider; (c) manage prescription billing; (d) effectuate

financial and contractual arrangements between and among drug companies, pharmacies, and health benefit providers; (e) provide mail order services; and (f) create and maintain formularies. Separate and apart from the health benefit providers, PBMs contract with drug manufacturers to negotiate rebates or discounts for the benefit of and on behalf of the health benefit providers, but they do not provide any additional service to the drug manufacturers.

155. One of the key ways PBMs exert influence over drug pricing is through drug formularies. Representing a list of drugs covered by a TPP, a formulary consists of drugs placed into different tiers. For example, tier 1 may include generic drugs and have the lowest patient out-of-pocket cost; tier 2 may include preferred branded drugs with a higher out-of-pocket cost; and tier 3 may include non-preferred branded drugs with the highest out-of-pocket cost. This design drives prescriptions to the lowest tiers, or toward generic or preferred branded drugs.

156. Drugs not included in the formulary are not paid for by a TPP and a physician is more likely to prescribe a drug that is covered by a patient's TPP formulary. Thus, placement on a formulary and on what tier directly impacts a drug's cost and utilization. Stated more explicitly, if a PBM excludes a drug from its formulary, the manufacturer will lose a major portion of sales from patients covered by that formulary. Conversely, if a PBM places a drug on a favorable tier in its formulary, the manufacturer will see a boost in the drug's sales volume and market

share. Consequently, drug manufacturers offered higher rebates to PBMs to secure preferential treatment.

157. Payments from self-insured health benefit providers, like the TPP Plaintiffs and TPP Class members, are routinely sent to the PBMs through the U.S. banking system by wire transfer, check, or other electronic funds transfers.

158. ***Rebate Aggregators.*** Rebate aggregators are a recent entrant into the pharmaceutical supply chain. Rebate Aggregators are often PBM-owned or affiliated and negotiate and collect the manufacturer rebates in exchange for favorable formulary placement, purportedly on behalf of PBMs or TPPs. Rebates are supposed to be passed through to these plan sponsors, but many Rebate Aggregators retain the rebates themselves.

159. ***PBM Mail Order Pharmacies.*** PBMs own and operate mail order pharmacies. The mail order pharmacies obtain drugs from the drug manufacturers and mail prescriptions directly to individuals covered by TPPs. TPPs then pay PBMs their negotiated payments for these drugs.

B. TPP Plaintiffs and TPP Class Members Employ PBMs as Agents and/or Fiduciaries and Directly Purchase from PBMs and Their Mail Order Pharmacies

160. The role of PBMs has changed since they were originally created in the 1960s and functioned largely as claims processors. In the decades since, PBMs have assumed an ever-expanding role as powerful entities within the pharmaceutical

distribution chain. The PBM industry has also substantially condensed in recent years. While previously there were nearly forty PBM entities, now just three PBMs (the PBM Defendants) cover roughly 80% of privately insured Americans. Moreover, each PBM is now affiliated with other significant players in the pharmaceutical chain, e.g., Express Scripts merged with Cigna and established the Rebate Aggregator Ascent; CVS bought Caremark (and now also owns Aetna) and established the Rebate Aggregator Zinc; and UnitedHealth Group acquired OptumRx and OptumRx established the Rebate Aggregator Emisar.

161. PBMs are in a position of superior knowledge and special expertise regarding the administration of prescription drug benefits and market their superior knowledge and special skills as a means of lowering costs for their TPP clients.

162. Health plans repose trust and confidence in and rely on PBMs to serve as their agents and/or fiduciaries with the Manufacturer Defendants in connection with negotiating drugs prices and formulary placement. Moreover, given the PBMs' specific expertise regarding the administration of prescription drug benefits, which PBMs themselves tout in order to gain health plan's business, health plan sponsors rely on PBMs as agents and/or fiduciaries to negotiate with drug manufacturers and obtain cost-reduction of prescription drugs. Lacking the resources or pharmaceutical expertise necessary to develop their own formularies, health plans generally rely entirely on PBMs for drug formulary decisions and accept what the PBMs offer.

Given this “invited reliance” on the special expertise and skill of PBMs, they maintain an agency and/or fiduciary relationship with respect to their health plan clients in connection with the management of their respective pharmacy benefit plans, the development of formularies as described below, and the negotiation of drug prices with manufacturers.

163. PBMs also create networks of pharmacies. These networks can include PBM-purchased pharmacies, PBM-consolidated pharmacies, PBM-affiliated retail pharmacies, and PBM mail order pharmacies (e.g., Caremark Rx, LLC, ESI Mail Pharmacy Service, Inc., and OptumRx, Inc.). “A PBM that owns a pharmacy (whether retail or mail) is considered vertically integrated” within the pharmaceutical distribution chain.⁴⁰ PBMs negotiate with these same pharmacies to set the amount those pharmacies will receive from PBM clients—i.e., health plans. These PBM pharmacies purchase directly from drug manufacturers,⁴¹ take possession of the drug products, and sell the products directly to consumers and health plans.

164. TPPs, like the TPP Plaintiffs and similarly situated Class members, directly purchase Insulin Drugs from the PBM Defendants via the PBM mail order

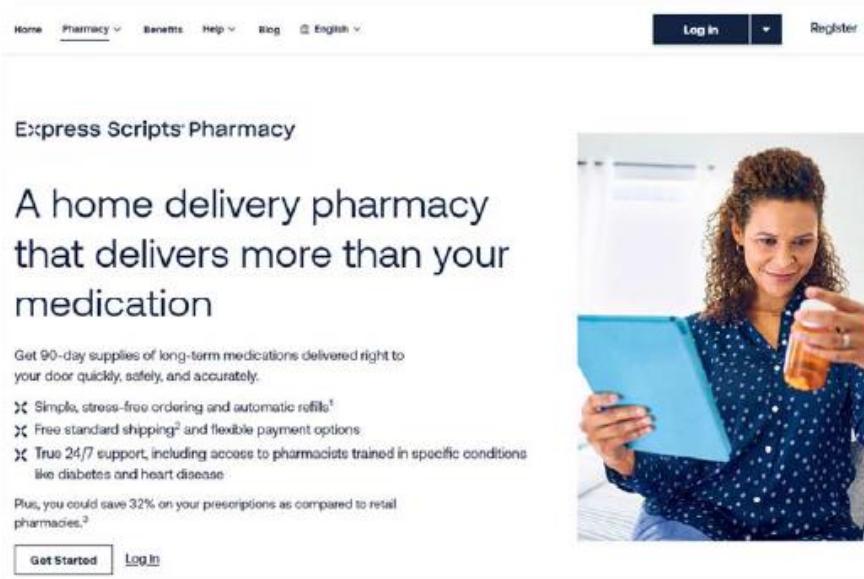
⁴⁰ *Pharmacy Benefit Managers: Ownership of Mail order Pharmacies* at xv, FTC (Aug. 2005), https://www.ftc.gov/sites/default/files/documents/reports/pharmacy-benefit-managers-ownership-mail-order-pharmacies-federal-trade-commission-report/050906pharmbenefitrpt_0.pdf.

⁴¹ *Id.* at 4.

pharmacies, and thus were directly and immediately harmed by Defendants' schemes. Each of the Manufacturer Defendants and each of the PBM Defendants intended and foresaw that TPP Plaintiffs and similarly situated Class members would, by paying artificially inflated list prices for the Insulin Drugs purchased from PBM mail order pharmacies, pay substantial overcharges due to Defendants' pattern of racketeering activity.

165. Each PBM Defendant offers mail order pharmacy services to be used by TPPs and/or their participants to purchase the Insulin Drugs. Typically, PBM mail order pharmacies sell 90-day supplies of drugs to customers who fill and pay (along with their health plan) for their prescription online. The mail order pharmacy then ships the purchase directly to the consumer.

Figure 3: Screenshot of Express Scripts Mail Order Pharmacy Site



166. PBMs increase their profits when they dispense drugs through a mail order pharmacy rather than through a retail pharmacy because when the drugs are dispensed through a PBM owned mail order pharmacy, the PBM captures the entire retail margin.

167. Critically, the prices PBM Defendants charge for the Insulin Drugs are based on the Manufacturer Defendants' prices. Therefore, the more the Manufacturer Defendants inflate their prices, the more money the PBM Defendants make through their mail order pharmacies.

168. To further increase these ill-gotten profits, the PBM Defendants engage in an arbitrage scheme. They collude with the Manufacturer Defendants to ensure that they always charge the highest price possible for the Insulin Drugs. Importantly, the PBM Defendants often know when the Manufacturer Defendants are going to raise their prices. The PBM Defendants purchase a significant volume of the Insulin Drugs before the price increase instituted by the Manufacturer Defendants goes into effect. Later, when the Manufacturer Defendants raise their price, the PBM Defendants charge their mail order customers based on the increased prices, not what they actually paid for the product before the price increase, and pocket the difference. The PBM Defendants make significant amounts of money at TPPs' expense through this arbitrage scheme.

C. Other Direct Purchaser Plaintiffs Directly Purchase from Manufacturer Defendants

169. Other Direct Purchaser Plaintiffs directly purchased Insulin Drugs from the Manufacturer Defendants, and thus were directly and immediately harmed by Defendants' schemes. Each of the Manufacturer Defendants and each of the PBM Defendants intended and foresaw that Other Direct Purchaser Plaintiffs would, by paying artificially inflated list prices for the Insulin Drugs, pay substantial overcharges due to Defendants' pattern of racketeering activity.

170. Rather than lower their prices to gain market share via formulary inclusion, the Manufacturer Defendants instead engaged in a scheme with the PBM Defendants to corrupt the supply chain by artificially inflating list prices in exchange for preferred formulary placement, shifting the cost of the bribes and kickbacks to purchasers of Insulin Drugs and sharing those financial benefits with the PBM Defendants.

171. But for the payment of bribes and kickbacks, and their achievement through list price increases, the Insulin Drugs would have had a lower list price, and Plaintiffs and Class members would have paid less for the Insulin Drugs. Plaintiffs and Class members have overpaid hundreds of millions of dollars for the Insulin Drugs purchased directly from the Manufacturer Defendants based on inflated list prices.

D. PBM Defendants and Manufacturer Defendants Have Ample Opportunity to Coordinate Pricing

172. Each Manufacturer Defendant is a member of the industry group Pharmaceutical Research and Manufacturers of America (“PhRMA”) and has routinely communicated via PhRMA meetings and platforms regarding the pricing of Insulin Drugs.

173. David Ricks (Eli Lilly’s Chairman and CEO), Paul Hudson (Sanofi’s CEO), and Douglas Langa (Novo Nordisk’s President and EVP of North American Operations), serve on PhRMA’s Board of Directors and/or as part of the PhRMA executive leadership team.

174. PBM Defendants also routinely communicate through direct interaction with their competitors and Manufacturer Defendants at trade associations, including the Pharmaceutical Care Management Association (“PCMA”) and industry conferences. Each PBM Defendant is a member of PCMA. Manufacturer Defendants are each affiliate members of PCMA.

175. PCMA is governed by PBM executives. As of August 2023, the Board of the PCMA included: Adam Kautzner (Express Scripts’s President), Dr. Patrick Conway (OptumRx’s CEO), and David Joyner (CVS Health’s Executive Vice President and President of Pharmacy Services at CVS Health).

176. Each year, high-level representatives and corporate officers from both PBM Defendants and Manufacturer Defendants attend PCMA conferences to meet

in person and engage in discussions, including those related to the prices of Insulin Drugs.

177. In fact, for at least the last eight years, all Manufacturer Defendants have been “Partners,” “Platinum Sponsors,” or “Presidential Sponsors” of these PBM conferences. Many of the forums at these conferences are specifically advertised as offering opportunities for private, non-public communications.

178. Representatives from each Manufacturer Defendant have routinely met privately with representatives from each PBM Defendant during PCMA’s Annual Meetings and Business Forum conferences each year.⁴²

179. In addition, all PCMA members, affiliates, and registered attendees of these conferences are invited to join PCMA-Connect, “an invitation-only LinkedIn Group and online networking community.”⁴³

180. Manufacturer Defendants and PBM Defendants have utilized PCMA meetings as opportunities to arrange lockstep price increases.

181. For example, on October 1, 2017, just days after Defendants had met at PCMA’s annual meeting on September 26 and 27, 2017, Sanofi increased Lantus’s list price by 3% and Toujeo’s list price by 5.4%, while Novo Nordisk recommended

⁴² *PCMA-Connect*, PCMA, <https://www.pcmanet.org/contact/pcma-connect/> (last visited Sept. 30, 2024).

⁴³ *Id.*

that their company make a 4% list price increase effective on January 1, 2018, to match the Sanofi increase.⁴⁴

182. Similarly, on May 30, 2014, a few weeks after PCMA’s 2014 spring conference, Novo Nordisk raised the list price of Levemir a matter of hours after Sanofi made its list price increase on Lantus.⁴⁵

183. PBM Defendants control the PCMA and have instituted numerous lawsuits and lobbying campaigns aimed at blocking drug-pricing transparency efforts, including recently suing the Department of Health and Human Services (“HHS”) to block the finalized HHS “rebate rule,” which would eliminate anti-kickback safe harbors for rebates and other payments from Manufacturer Defendants to PBMs and instead offer them as direct-to-consumer discounts.

184. Additionally, communications among PBM Defendants are facilitated by frequent moves among executives from one PBM Defendant to another. For example:

- a. Mark Thierer worked as an executive at Caremark Rx (now CVS Caremark) prior to becoming the CEO of OptumRx in 2016 (and also served as Chairman of the Board for PCMA starting in 2012);
- b. CVS Health’s current President and CEO Karen Lynch held an executive position at Cigna;

⁴⁴ Staff of S. Comm. on Fin, 116th Cong., Rep. on Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug 4 (Comm. Print 2021), <https://www.finance.senate.gov/imo/media/doc/Insulin%20Committee%20Print.pdf>.

⁴⁵ *Id.* at 47.

- c. Amar Desai served as President for Health Care Delivery at CVS Health before joining Optum Health, where he now serves as CEO.
- d. Trip Hofer served in leadership at CVS Health before becoming CEO of Behavioral Health for Optum Health.
- e. Bill Wolfe was the President of the PBM Catalyst Rx (now OptumRx) prior to becoming the President of Aetna Rx in 2015 (and also served as a PCMA board member from 2015-2017 while with Aetna Rx);
- f. Derica Rice, former EVP for CVS Health and President of CVS Caremark, previously served as EVP and CFO for Eli Lilly;
- g. Duane Barnes was the Vice President of Medco (now Express Scripts) before becoming Division President of Aetna Rx in 2006 (and also served as a PCMA board member);
- h. Everett Neville was the Division President of Aetna Rx before becoming Senior Vice President of Express Scripts;
- i. Albert Thigpen was a Senior Vice President at CVS Caremark for 11 years before becoming a Senior Vice President at OptumRx in 2011;
- j. Harry Travis was the Chief Operating Officer at Medco (now Express Scripts) before becoming a Vice President at Aetna Rx in 2008; he also served as SVP Member Services Operations for CVS Caremark from 2020-2022; and
- k. Bill Kiefer was a Vice President of Express Scripts for 14 years before becoming Senior Vice President of Strategy at OptumRx in 2013.

E. Defendants' Manipulation of PBM Incentives and Resulting Profits

185. The pricing and kickback scheme at issue here affords Manufacturer Defendants the ability to pay PBM Defendants secret, but significant, payments in exchange for favorable and unwarranted formulary placement that is contrary to the interest of the TPP. Specifically, the formulary construction by the PBM Defendants

favors more expensive drugs, including the Insulin Drugs, even though less expensive alternative drugs are available.

186. This allows Manufacturer Defendants to garner greater sales at higher prices. Those higher prices more than offset the secret fees and rebates (i.e., bribes) that they pay to PBM Defendants for the unwarranted favorable formulary placement. In this way, the Manufacturer Defendants increase their revenues from sales without decreasing their profit margins. Manufacturer Defendants also use the inflated price to earn hundreds of millions of dollars in additional tax breaks by basing their deductions for donated insulins on the inflated list price.

187. PBM Defendants in turn make a profit in a multitude of ways relevant here: First, they keep the difference between what they pay retail pharmacies for drugs (a percentage of the list price plus dispensing costs) and what health plans pay them (a higher percentage of the list price plus dispensing costs). Second, PBMs extract rebates from drug manufacturers in exchange for the placement of the manufacturers' drugs on PBM formularies and pocket a portion of the difference between a drug's list price and the net price they negotiate with its manufacturer (through rebates and fees tied to the drugs' list price)—i.e., the “spread” between prices. Third, PBMs sell prescription drugs to TPPs through the mail order pharmacies that they own and operate. Fourth, PBMs retain the entirety of undisclosed and/or hidden rebates and fees they receive. The drug manufacturers'

“rebate” arrangements are meant to create an incentive for PBMs to negotiate lower *real* drug prices. But Manufacturer Defendants know that this business model can be manipulated such that PBM Defendants no longer have an incentive to control costs.

188. As a 2022 report by the Community Oncology Alliance explains:

Among the different sources of revenue, the most prolific by far is in the form of rebates from pharmaceutical manufacturers that PBMs extract in exchange for placing the manufacturer’s drug(s) on a plan sponsor’s formulary or encouraging utilization of the manufacturer’s drug(s) . . . [T]he growing number and scale of rebates is the primary fuel for today’s high drug prices. The truth is that PBMs have a vested interest in having drug prices remain high, and extracting rebates off these high prices. PBM formularies tend to favor drugs that offer higher rebates over similar drugs with lower net costs and lower rebates.⁴⁶

189. For the majority of prescription drug transactions, only the PBM Defendants are privy to the amount that any other entity in the supply chain is paying or receiving for drugs, granting Defendants the opportunity to extract billions of dollars from this payment and supply chain without detection.

190. Furthermore, rapid consolidation in the PBM industry has given PBM Defendants considerable market power, controlling roughly 80% of drug benefits for over 270 million Americans. PBM Defendants reported revenues of more than \$400 billion in 2022.

⁴⁶ Cmty. Oncology All. Comment Letter on Harm of Pharmacy Benefit Manager Integration (May 24, 2022), <https://communityoncology.org/coa-formal-comments-to-ftc-on-harm-of-pharmacy-benefit-manager-integration/>.

191. PBMs have substantial negotiating power when negotiating formulary placement for interchangeable drugs—that is, drugs in the same therapeutic class perceived to have similar efficacy and risk profiles. That is the case with the Insulin Drugs. In such a scenario, the drug companies should compete for formulary access by lowering their list prices.

192. But Defendants have found a way to game this system. As Defendants have realized, the spread between net and list price can be enlarged by *raising list prices* while holding *net prices constant* (or decreasing them slightly). In exchange for this spread enlargement, PBM Defendants agree with Manufacturer Defendants, either explicitly or implicitly, to favor or at least not disfavor, the drug with the most elevated list price. Manufacturer Defendants know that when they increase the list prices of their insulins, PBM Defendants can earn substantially greater revenues so long as net prices remain constant. In addition, the PBM Defendants' profits are pushed even higher by their retention of secret payments through illicit “fees” and undisclosed and unearned “rebates.”

193. The perverse incentives for higher list prices (and consequent overpayments), was described in a recent report on the drug industry:

At the whole-market level, we sense that the price protection rebate arbitrage game is driving manufacturers to higher list price increases than would otherwise occur, particularly on the eve of a general election. Price protection rebates between brand manufacturers and PBMs are common, as are fixed rebate agreements between PBMs and a significant portion of their plan sponsors. When brand manufacturers’

[list price] increases exceed the price protection threshold, the manufacturers rebate the difference to PBMs, who pocket the difference when these price protection rebates grow faster than the PBMs' fixed rebate commitments to plan sponsors. Thus all else equal in a given category, the product with the more rapid list price increases is more profitable to the PBM. Manufacturers, realizing this, don't want their products disadvantaged, and accordingly are driven to keep their rates of list price inflation at least as high, and ideally just a bit higher, than peers'. Durable list price inflation is the natural result. Net price inflation is unaffected, but unit volumes suffer as higher list prices directly impact consumers who have not yet met their deductibles.⁴⁷

194. Defendants here have used the phony list prices to their advantage.

Manufacturer Defendants use the spread between prices to provide kickbacks to PBM Defendants in exchange for formulary status. These payments once called "rebates" are now called "administrative fees," "volume discounts," "service fees," "inflation fees," or other industry terms designed to obfuscate the substantial sums being secretly exchanged between the PBM Defendants and the Manufacturer Defendants. This pricing and kickback scheme enables Defendants to maintain preferred formulary positions without reducing their net prices.

195. Manufacturer Defendants understand that PBM Defendants make more money as prices increase. As the U.S. Senate Finance Committee has explained:

[B]oth Eli Lilly and Novo Nordisk executives, when considering lower list prices, were sensitive to the fact that PBMs largely make their

⁴⁷ Richard Evans, Scott Hinds, & Ryan Baum, *US Rx Net Pricing Trends Thru 2Q16* at 36, SSR LLC (Oct. 5, 2016).

money on rebates and fees that are based on a percentage of a drug's list price.⁴⁸

196. The documents eventually released by the Senate Finance Committee also show how the Manufacturer Defendants' pricing strategy focuses on the PBM Defendants' profitability. In an internal Novo Nordisk email dated August 6, 2015, executives considered delaying increasing the price of an Insulin Drug to make the price increase more profitable for CVS Caremark, stating:

Should we take 8/18 [for a price increase], as agreed to by our [pricing committee], or do we recommend pushing back due to the recent CVS concerns on how we take price? . . . We know CVS has stated their disappointment with our price increase strategy (ie taking just after the 45th day) and how it essentially results in a lower price protection, admin fee and rebate payment for that quarter/time after our increase . . . it has been costing CVS a good amount of money.⁴⁹

197. Manufacturer Defendants also understand that because of the PBM Defendants' market dominance, most TPPs accept the baseline national formularies offered by the PBMs with respect to Insulin Drugs.

198. Over the past several years, the Manufacturer Defendants have raised prices in unison and have paid correspondingly larger rebates and other price

⁴⁸ Press Release, Grassley, Wyden Release Insulin Investigation, Uncovering Business Practices Between Drug Companies and PBMs That Keep Prices High, S. Fin. Comm. (Jan. 14, 2021), <https://www.finance.senate.gov/imo/media/doc/Insulin%20Committee%20Print.pdf>.

⁴⁹ Staff of S. Comm. on Fin, 116th Cong., Rep. on Insulin, Letter from Raphael A. Prober, Counsel for Novo Nordisk Inc., to Charles E. Grassley & Ron Wyden at NNI-FINANCE-001793, S. Fin. Comm. (Mar. 8, 2019), https://www.finance.senate.gov/imo/media/doc/Novo_Redacted.pdf.

concessions to the PBM Defendants. In exchange for the Manufacturer Defendants artificially inflating their prices and paying the PBM Defendants substantial amounts, the PBM Defendants grant the Manufacturer Defendants' Insulin Drugs preferred status on their formularies. During the relevant period, the rebate amounts for Insulin Drugs (as a proportion of the list price) grew year-over-year while list prices themselves increased.

199. The Senate Finance Committee released a report on January 14, 2021 detailing the "opaque" business dealings between manufacturers and PBMs, including the PBM Defendants, that led to the higher cost of insulin for the past 15 years.⁵⁰ The report pinned most of the blame on PBMs for encouraging drugmakers to raise their list price to offer greater rebates and payments to PBMs and ensure that their product is included on the formulary "absent significant advances in the efficacy of the drugs."⁵¹ The report also states:

These price increases appear to have been driven, in part, by tactics PBMs employed [beginning] in the early 2010s. At that time, PBMs began to more aggressively pit manufacturers against each other by implementing formulary exclusions in the insulin therapeutic class, which effectively stopped manufacturers from reaching large blocks of patients. . . . As a result, pharmaceutical manufacturers continued to raise WAC prices aggressively—increases that were often closely

⁵⁰ Staff of S. Comm. on Fin, 116th Cong., Rep. on Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug 6, 65 (Comm. Print 2021), <https://www.finance.senate.gov/imo/media/doc/Insulin%20Committee%20Print.pdf>.

⁵¹ *Id.* at 2.

timed with price changes made by competitors (a practice that has been referred to as “shadow pricing”).⁵²

200. For example, in 2016, as PBMs began to threaten formulary exclusion based on new entrants in the insulin market, Manufacturer Defendants Sanofi and Novo Nordisk enhanced their rebate offers. At the same time, Eli Lilly introduced Basaglar, a follow-on biologic to Lantus. Basaglar is a long-acting insulin and is clinically very similar to Sanofi’s Lantus. Because of its near clinical equivalence, Basaglar posed a competitive threat in the long-acting insulin market. Express Scripts communicated to Sanofi that “with the right competitive price, [it] would not have significant challenges moving [from Lantus and Toujeo] to Basaglar” and that Sanofi must enhance its current rebate rate of 42% to maintain access for their basal insulins.⁵³

201. For the Manufacturer Defendants, the mere threat of exclusion has pressured them to offer substantially greater rebates to maintain formulary position. This is due to the fact that formulary exclusions are likely to cause significant loss of a manufacturer’s market share, leading to lower revenue. In contrast, being the exclusive therapy on a formulary has the opposite effect. This dynamic incentivizes Manufacturer Defendants to offer large discounts to acquire or maintain the formulary status of their drugs. Accordingly, the formulary exclusions have led to a

⁵² *Id.*

⁵³ *Id.* at 61.

market dynamic in which Manufacturer Defendants offer larger rebates in order to avoid the negative impacts of formulary exclusion, to which the result is higher list prices.

202. In addition to increased rebate demands, PBM Defendants have also negotiated and received increasingly large purported administrative fees from Manufacturer Defendants during the relevant period. These so-called administrative fees typically are based on a percentage of the drug price—as opposed to a flat fee—such that even if the actual “administrative” cost associated with processing two drugs is the same, the “administrative fee” would be correspondingly higher for the higher-priced drug, which again creates (by design) a perverse incentive to give preference to more expensive drugs.

203. Moreover, PBM Defendants’ contracts with TPPs, like the TPP Plaintiffs and similarly situated TPP Class members, narrowly define “rebates” by tying them to patient drug utilization. Thus, rebates for formulary placement (which are not tied to patient drug utilization) are characterized and disguised as “administrative fees” that are not remitted to TPPs. Such payments are beyond a TPP’s contractual audit rights because those rights are limited to “rebate” payments and these purported “administrative fees” have been carved out from the definition of “rebates.”

204. Administrative fees (like rebates tied to formulary placement) can make up a substantial portion of the total dollar amount of drug company payments to a PBM. According to David Dross, a pharmacy-benefits consultant who has been cited in Senate testimony, administrative fees can amount to 25-30% of total payments from drug companies like Manufacturer Defendants.⁵⁴ Express Scripts revealed in a 2017 lawsuit that it filed against one drug manufacturer that it kept 13 times more in administrative fees than it passed back to its clients through acknowledged “rebates.”⁵⁵

205. A recent study by the Pew Charitable Trusts estimated that between 2012 and 2016 the amount of administrative and other fees that the PBMs received from the Manufacturers *tripled*, reaching more than \$16 billion.⁵⁶ According to the study, although rebates were sent to TPPs during this period, PBMs retained the same volume of rebates in dollar terms, due to the overall growth in rebate volume,

⁵⁴ David Dross, *Will Point-of-Sale Rebates Disrupt the PBM Business?*, Mercer (July 31, 2017), <https://www.mercer.us/our-thinking/healthcare/will-point-of-sale-rebates-disrupt-the-pbm-business.html>.

⁵⁵ *Express Scripts Lawsuit Should Raise Everyone’s Eyebrows*, Nat’l Prescription Coverage Coalition, <http://nationalprescriptioncoveragecoalition.com/express-scripts-lawsuit-should-raise-everyones-eyebrows/> (last visited Oct. 1, 2024). According to Express Scripts’ complaint, it entered “rebate agreements” with the drug manufacturer, which required the manufacturer to pay Express Scripts far more in “administrative fees” than the manufacturer paid in “formulary rebates.” *Id.*

⁵⁶ *The Prescription Drug Landscape, Explored*, Pew Charitable Trusts, (Mar. 8, 2019), <https://www.pewtrusts.org/en/research-and-analysis/reports/2019/03/08/the-prescription-drug-landscape-explored>.

while administrative fees and spread pricing further offset reductions in retained rebate volumes.

206. Thus—and contrary to their public representations—PBM Defendants’ negotiations and agreements with Manufacturer Defendants (and the formularies that result from these agreements) have caused and continue to cause precipitous price increases for Insulin Drugs. PBM Defendants benefit from the size of the spreads between list and net price. PBM Defendants boast of the “increased rebates” they have achieved, when, in reality, the “discounts” they have obtained are simply reductions off artificially-inflated list prices. In other words, these “discounts” are not discounts at all.

207. While PBM Defendants pass some percentage of rebates and fees back to the TPPs, they also retain a large portion of such moneys, in part through misleading labeling of what are essentially kickback payments received from drug companies like Manufacturer Defendants. The PBM Defendants have broad discretion in how they label rebates or “fees” received from the drug manufacturers and they use this discretion to disguise and conceal the amounts of money they receive from the manufacturers. This lack of transparency enables PBM Defendants to label the payments that they negotiate with Manufacturer Defendants such that they retain control over the amount of money they keep for themselves. Thus, the

hard bargains PBM Defendants purport to drive for their clients are, in reality, for the benefit of PBM Defendants themselves.

208. PBMs have written their contracts to retain for themselves all other payments from drug companies like the Manufacturer Defendants, including, among other things, discounts, purported “administrative or other fees,” and/or side deals, and thus, the result is that PBM Defendants profit handsomely from undisclosed and/or mislabeled “rebates.”⁵⁷ Because these rebates buy favorable formulary placement, the Manufacturer Defendants are able to raise their prices to cover more than the amount of the rebates, without losing any sales due to their unduly high prices.

209. Adding another layer of opaqueness, in recent years PBM Defendants each formed separate Rebate Aggregators. Beginning in 2019, Express Scripts formed Ascent, followed by CVS’s formation of Zinc in 2020, and Optum’s formation of Emisar in 2021.

210. PBMs now use these Rebate Aggregators to manage rebate negotiations and contracting services with drug manufacturers and TPP clients⁵⁸ and

⁵⁷ Linda Cahn, *How to Dramatically Decrease Your MCO’s Rx Coverage Costs*, Managed Care Mag. (Apr. 2008), https://www.managedcaremag.com/archives/0804/0804.mco_rx.html [https://www.managedcaremag.com/archives/0804/0804.mco_rx.html].

⁵⁸ Press Release, *FTC Deepens Inquiry into Prescription Drug Middlemen*, FTC (May 17, 2023), <https://www.ftc.gov/news-events/news/press-releases/2023/05/ftc-deepens-inquiry-prescription-drug-middlemen>.

to conceal and disguise rebates (actually bribes) as administrative “fees.” Notably, “the spate of GPO [Rebate Aggregator] launches by PBMs came as Congress was debating legislation that would establish new transparency requirements for PBMs[.]”⁵⁹

211. PBM Defendants, by and through their respective agent Rebate Aggregators, solicit bids from drug manufacturers using rebate grids that manufacturers fill out with different rebate rates for different levels of exclusivity. In addition, PBM Defendants, through their respective Rebate Aggregators, extract administrative fees from drug manufacturers attributed to implementing the rebate program, negotiating and contracting clients’ participation in the rebate program, overseeing rebate eligibility compliance, and calculating and invoicing rebates attributable to eligible drug utilization. PBM Defendants, through their respective Rebate Aggregators, may also extract data fees from drug manufacturers for granting access to portals that contain various data for the manufacturers’ drugs.

212. The appearance of Rebate Aggregators in the already complicated chain of financial transactions between drug manufacturers and PBMs and between TPPs and PBMs creates an additional layer from which PBMs can extract unlawful monies camouflaged as fees without adding any value. A 2022 Drug Channels analysis of

⁵⁹ Deborah Abrhams Kaplan, *PBMs are creating GPOs, and Stirring Debate as to Why*, Managed Health Care Executive (July 12, 2022), <https://www.managedhealthcareexecutive.com/view/pbms-are-creating-gpos-and-stirring-debate-as-to-why>.

the Texas Department of Insurance data from 2016 to 2021 revealed “a compelling and fairly consistent tale about what happened to the manufacturers’ payments to PBMs.”⁶⁰ The Drug Channels analysis concluded that the PBMs retained hundreds of millions of dollars, by keeping 7% to 21 % of the manufacturers’ total payments.

213. The PBM Defendants carefully guard the revenue stream from their rebate aggregator activities, by concealing them through convoluted corporate relationships and not disclosing them in their quarterly SEC filings.

214. In addition, the foreign incorporation of Optum’s and Express Scripts’ Rebate Aggregators creates new hurdles for TPPs seeking formal accountings of the parties’ rebates and fees collections. To verify any such accountings in person, a TPP would be required to travel to a different country just to confirm all accountings were accurate in order for TPPs to submit proper reports to DHHS or state agencies in accordance with federal laws.

215. As summarized by the recent Community Oncology Alliance report:⁶¹

PBMs have increasingly “delegated” the collection of manufacturer rebates to “rebate aggregators,” which are often owned by or affiliated with the PBMs, without seeking authorization from plan sponsors and

⁶⁰ *Texas Shows Us Where PBMs’ Rebates Go*, Drug Channels (Aug. 9, 2022), <https://www.drugchannels.net/2022/08/texas-shows-us-where-pbms-rebates-go.html#:~:text=For%202021%2C%20PBMs%20retained%20%24752,95%25%20or%20more%20of%20rebates>.

⁶¹ Pharmacy Benefit Manager Exposé: How PBMs Adversely Impact Cancer Care While Profiting at the Expense of Patients, Providers, Employers, and Taxpayers at 15-16, Cmtys. Oncology All. & Frier Levitt, (Feb. 2022), https://communityoncology.org/wp-content/uploads/2022/02/COA_FL_PBM_Expose_2-2022.pdf.

without telling plan sponsors. . . . Even some of the major PBMs (i.e., the “Big Three” PBMs) sometimes find themselves contracting with other PBMs’ rebate aggregators for the collection of manufacturer rebates. . . . In both the private sector and with respect to government health care programs, the contracts regarding manufacturer rebates (i.e., contracts between PBMs and rebate aggregators, as well as contracts between PBMs/rebate aggregators and pharmaceutical manufacturers) are not readily available to plan sponsors.

216. Growing concerns about rebate aggregators and the black box they create in the provision of life-saving diabetes medications to patients who need them have led to the Federal Trade Commission (“FTC”) filing suit against Zinc, Ascent, and Emisar, along with PBM Defendants, alleging violations of Section 5 of the FTC Act by illegally inflating list prices of critical drugs, including certain Insulin Drugs.⁶²

F. Defendants Downplay the Pricing and Kickback Scheme for Insulin Drugs and Its Resulting Harms to Congress

217. On April 10, 2019, the U.S. House of Representatives Committee on Energy and Commerce held a hearing on industry practices titled, “Priced Out of a Lifesaving Drug: Getting Answers on the Rising Cost of Insulin.”⁶³

⁶² Complaint, *In re Caremark Rx, LLC et al.*, No. 9437 (Sept. 20, 2024), https://www.ftc.gov/system/files/ftc_gov/pdf/d9437_caremark_rx_zinc_health_services_et_al_part_3_complaint_corrected_public.pdf.

⁶³ *Priced Out of a Lifesaving Drug: Getting Answers on the Rising Cost of Insulin:* Hearing Before the H. Subcomm. on Oversight and Investigations, 116th Cong. (2019), <https://www.congress.gov/116/meeting/house/109299/documents/HHRG-116-IF02-Transcript-20190410.pdf> (hereinafter, “Priced Out of a Lifesaving Drug”).

218. Representatives from Defendants testified under oath at the hearing and admitted that the price for insulin had increased exponentially over the past 15 years. Representatives for Defendants also conceded that the price that diabetics pay out-of-pocket for insulin is too high. For example:

- a. Dr. Sumit Dutta, SVP and Chief Medical Officer of OptumRx since 2015, testified: “A lack of meaningful competition allows [M]anufacturers to set high [list] prices and continually increase them which is odd for a drug that is nearly 100 years old and which has seen no significant innovation in decades. These price increases have a real impact on consumers in the form of higher out-of-pocket costs.”⁶⁴
- b. Thomas Moriarty, General Counsel for CVS, admitted: “A real barrier in our country to achieving good health is cost, including the price of insulin products which are too expensive for too many Americans. Over the last several years, list prices for insulin have increased nearly 50 percent. And over the last 10 years, list price of one product, Lantus, rose by 184 percent.”⁶⁵
- c. Mike Mason, Senior Vice President of Eli Lilly, testified when discussing how much diabetics pay out-of-pocket for insulin: “it’s difficult for me to hear anyone in the diabetes community worry about the cost of insulin. Too many people today don’t have affordable access to chronic medications.”⁶⁶
- d. Kathleen Tregoning, Executive Vice President External Affairs at Sanofi, testified: “Patients are rightfully angry about rising out-of-pocket costs for many medicines and we all have a responsibility to address a system that is clearly failing too many people... we recognize the need to address the very real challenges of affordability... [S]ince 2012, average out-of-pocket costs for Lantus have risen approximately 60 percent...”⁶⁷

⁶⁴ *Id.* at ¶¶ 919-24.

⁶⁵ *Id.* at ¶¶ 705-10.

⁶⁶ *Id.* at ¶¶ 461-63.

⁶⁷ *Id.* at ¶¶ 616-18, 643-44, 657-59.

e. Doug Langa, Executive Vice President of Novo Nordisk, testified: “On the issue of affordability . . . I will tell you that at Novo Nordisk we are accountable for the list prices of our medicines. We also know that list price matters to many, particularly those in a high-deductible health plan and those that are uninsured.”⁶⁸

219. None of the testifying executives claimed that the significant increase in the price of insulin was related to competitive factors such as increased production costs or improved clinical benefit.

220. Instead, the written testimony of Doug Langa, Novo Nordisk’s President, recognized “misaligned incentives” that have led to higher drug costs, including for insulin:

Chief among these misaligned incentives is the fact that the rebates pharmaceutical companies pay to PBMs are calculated as a percentage of WAC [list] price. That means a pharmaceutical company fighting to remain on formulary is constrained from lowering WAC price, or even keeping the price constant, if a competitor takes an increase. This is because PBMs will then earn less in rebates and potentially choose to place a competitor’s higher-priced product on their formulary to the exclusion of others.⁶⁹

221. Likewise, Mr. Langa’s responses to questions for the record conceded that “[t]he disadvantage of a system in which administrative fees are paid as a percentage of list price is that there is increased pressure to keep list prices

⁶⁸ *Id.* at ¶¶ 531-35.

⁶⁹ Testimony of Douglas J. Langa Novo Nordisk Inc. Before the H. Comm. on Energy & Com. Subcomm. on Oversight and Investigations at 3 (Apr. 10, 2019), <https://www.congress.gov/116/meeting/house/109299/witnesses/HHRG-116-IF02-Wstate-LangaD-20190410.pdf>.

high. . . .”⁷⁰ The hearing transcript records Mr. Langa’s further comments in this regard:

So as you heard last week from Dr. Cefalu from the ADA [American Diabetes Association], there is this perverse incentive and misaligned incentives and this encouragement to keep list prices high. And we’ve been participating in that system because the higher the list price, the higher the rebate . . . There’s a significant demand for rebates . . . we’re spending almost \$18 billion a year in rebates, discount, and fees, and we have people with insurance with diabetes that don’t get the benefit of that.⁷¹

222. Eli Lilly admitted that it raises list prices as a quid pro quo for formulary positions. At the April 2019 Congressional hearing, Mike Mason, Senior Vice President of Eli Lilly, testified:

Seventy-five percent of our list price is paid for rebates and discounts . . . \$210 of a vial of Humalog is paid for discounts and rebates. . . We have to provide rebates [to PBMs] in order to provide and compete for that [formulary position] so people can use our insulin.⁷²

In the very next question, Mr. Langa of Novo Nordisk was asked: “[H]ave you ever lowered a list price?” His answer: “We have not.”⁷³

⁷⁰ Questions for the Record, Responses of Douglas J. Langa Novo Nordisk Inc. at 9, Before the H. Comm. on Energy & Com. Subcomm. on Oversight and Investigations Hearing on “Priced Out of Lifesaving Drugs: Getting Answers on the Rising Cost of Insulin” (Apr. 10, 2019), <https://www.congress.gov/116/meeting/house/109299/witnesses/HHRG-116-IF02-Bio-LangaD-20190410-U2.pdf>.

⁷¹ Priced Out of a Lifesaving Drug, ¶¶ 987-91, 994, 1103-05

⁷² *Id.* at ¶¶ 979, 984-85, 1201-02.

⁷³ *Id.* at ¶¶ 1203-05.

223. Sanofi's Executive Vice President for External Affairs, Kathleen Tregoning, similarly testified:

The rebates is [sic] how the system has evolved . . . I think the system became complex and rebates generated through negotiations with PBMs are being used to finance other parts of the healthcare system and not to lower prices to the patient.⁷⁴

224. Her written response to questions for the record acknowledged that "it is clear that payments based on a percentage of list price result in a higher margin [for PBMs] for the higher list price product than for the lower list price product."⁷⁵

225. PBM Defendants also conceded at the April 2019 Congressional hearing that they grant preferred, or even exclusive, formulary position because of the secret payments made to them by Manufacturer Defendants.

226. For example, in her responses to questions for the record, Amy Bricker, former President of Express Scripts, a former PCMA board member, and now an executive at CVS Health, confirmed that "manufacturers lowering their list prices" would give patients "greater access to medications."⁷⁶ Yet when asked to explain

⁷⁴ *Id.* at ¶¶ 1123, 2409-12.

⁷⁵ Questions for the Record, Responses of Kathleen Tregoning Before the H. Comm. on Energy & Com. Subcomm. on Oversight and Investigations, Hearing on "Priced Out of Lifesaving Drugs: Getting Answers on the Rising Cost of Insulin" (Apr. 10, 2019), <https://www.congress.gov/116/meeting/house/109299/witnesses/HHRG-116-IF02-Bio-TregoningK-20190410-U2.pdf>.

⁷⁶ Questions for the Record Responses of Amy Bricker, Comm. on Energy and Commerce, Hearing on Priced Out of Lifesaving Drugs: Getting Answers on the Rising Cost of Insulin (Apr. 10, 2019), <https://www.congress.gov/116/meeting/house/109299/witnesses/HHRG-116-IF02-Bio-BrickerA-20190410-U2.pdf>.

why Express Scripts did not grant an insulin with a lower list price preferred formulary status, she answered: “Manufacturers do give higher discounts [i.e., payments] for exclusive [formulary] position . . .” When asked why the PBM would not include both costly and lower-priced insulin medications on its formulary, Ms. Bricker stated: “We’ll receive less discount in the event we do that.”⁷⁷

227. As Dr. Dutta, Senior Vice President of OptumRx, reasoned, the cheaper list-priced alternative Admelog is not given preference on the formulary because “it would cost the payer more money to do that . . . [b]ecause the list price is not what the payer is paying. They’re paying the net price.”⁷⁸ In other words, under the pricing and kickback scheme, PBMs and manufacturers can make a drug with a lower list price effectively more expensive for payors and then ostensibly save payors from that artificially inflated price by giving preference to drugs that had higher list prices to begin with (yielding higher payments to the PBMs).

228. While all Defendants acknowledged before Congress their participation in conduct integral to the pricing and kickback scheme, none revealed its inner workings or the connection between their coordination and the economic harm that payors, like TPP Plaintiffs and TPP members of the Class, and their beneficiaries were unwittingly suffering. Instead, to obscure the true reason for precipitous price

⁷⁷ Priced Out of a Lifesaving Drug, ¶¶ 1345-46, 1354-55.

⁷⁸ *Id.* at ¶¶ 1392-95.

increases, each Defendant group pointed the finger at the other as the more responsible party.

229. The PBM Defendants testified to Congress that the Manufacturer Defendants are solely responsible for their list price increases and that the payments that the PBMs receive are not correlated to rising insulin prices.

230. This testimony is false. The amount the Manufacturer Defendants kick back to the PBM Defendants is directly correlated to an increase in list prices. On average, a \$1 increase in payments to PBMs is associated with a \$1.17 increase in list price.⁷⁹ Thus, reducing or eliminating the secret kickbacks to PBMs would lower prices and reduce out-of-pocket expenditures.

231. Novo Nordisk's President, Doug Langa, submitted written testimony to Congress acknowledging "there is no doubt that the WAC [list] price is a significant component" of "what patients ultimately pay at the pharmacy counter."⁸⁰ Yet, Manufacturer Defendants urged upon Congress the fiction that the PBMs were solely to blame for insulin prices because of their demands for rebates in exchange

⁷⁹ Neeraj Sood, Rocio Ribero, Martha Ryan, Karen Van Nuys, USC Schaeffer, The Association Between Drug Rebates and List Prices (Feb. 11, 2020), <https://healthpolicy.usc.edu/research/the-association-between-drug-rebates-and-list-prices/>.

⁸⁰ Testimony of Douglas J. Langa Novo Nordisk Inc. Before the H. Comm. on Energy & Com. Subcomm. on Oversight and Investigations at 3 (Apr. 10, 2019), <https://www.congress.gov/116/meeting/house/109299/witnesses/HHRG-116-IF02-Wstate-LangaD-20190410.pdf>.

for formulary placement. Manufacturer Defendants claimed their hands were tied and sought to conceal their misconduct by suggesting that they have not profited from rising insulin prices.

232. Given Manufacturer Defendants' claims that rebates were the sole reason for rising prices, each was asked directly during the Congressional hearing to guarantee it would decrease list prices if rebates were restricted or eliminated. The spokespersons for Eli Lilly, Novo Nordisk, and Sanofi all said only that they would "consider it."⁸¹

G. Recent Government and Regulatory Investigations Spotlight Defendants' Conduct

233. Recently, the Defendants' fraudulent scheme has come under additional scrutiny from Congress and regulators.

234. In 2021, the U.S. House of Representatives Committee on Oversight and Reform issued a report following its investigation into drug pricing ("Drug Pricing Investigation").⁸² The House's report included inquiry into the Manufacturer Defendants' diabetes medication pricing strategies,⁸³ and concluded: "Every company in the Committee's investigation engaged in one or more strategies to

⁸¹ Priced Out of a Lifesaving Drug, ¶¶ 2068, 2070, 2077-79.

⁸² Staff of H. Comm. on Oversight and Reform, 117th Cong., Rep. on Drug Pricing Investigation 66 n.344 (2021), <https://oversightdemocrats.house.gov/sites/evo-subsites/democrats-oversight.house.gov/files/DRUG%20PRICING%20REPORT%20WITH%20APPENDIX%20v3.pdf>

⁸³ *Id.* at iii.

suppress competition from generics or biosimilars, and keep prices high.”⁸⁴ It continued:

Insulin manufacturers have also used secondary patents to extend their market monopolies. A 2020 study by the State of Colorado found, “Many insulin products have received additional patents, exclusivities, and extensions, adding decades of protection and monopoly prices.” According to this study, secondary patents enabled Eli Lilly to add 17 years of protection for Humalog, Novo Nordisk to add 27 years of protection for NovoLog, and Sanofi to add 28 years of protection for Lantus.⁸⁵

235. On June 7, 2022, the FTC began an investigation into PBM rebating practices.⁸⁶

236. On May 10, 2023, the U.S. Senate Committee on Health, Education, Labor, and Pensions held a hearing titled, “The Need to Make Insulin Affordable for All Americans.” At this hearing, the CEOs and presidents of the Manufacturer and PBM Defendants doubled down on their testimony to Congress in 2019. Notably, the Chair and CEO of Eli Lilly, David Ricks, testified that Eli Lilly raised list prices and agreed to pay ever-increasing rebates to PBMs in exchange for formulary placement stating:

Getting on formulary is the best way to ensure most people can access our medicines affordably . . . But that requires manufacturers to pay ever-increasing rebates and fees, which can place upward pressure on

⁸⁴ *Id.* at 85.

⁸⁵ *Id.* at 81.

⁸⁶ See Press Release, FTC Launches Inquiry Into Prescription Drug Middlemen Industry (June 7, 2022), <https://www.ftc.gov/news-events/news/press-releases/2022/06/ftc-launches-inquiry-prescription-drug-middlemen-industry>.

medicines' list prices . . . Last year alone, to ensure our medicines were covered, Lilly paid more than \$12 billion in rebates for all our medicines, and \$1 billion in fees.⁸⁷

237. Similarly, the CEO of Sanofi, Paul Hudson, asserted that PBMs prefer drugs with higher list prices and that the manufacturers have responded to this PBM preference accordingly. In discussing one drug Sanofi introduced with a lower list price, Hudson explained that despite this lower pricing for this drug: "It just didn't get listed in any way. If price is really the motivator, it would have been listed."⁸⁸

238. On May 23, 2023, the United States House Committee on Oversight and Accountability held a hearing on: *The Role of Pharmacy Benefit Managers in Prescription Drug Markets: Self-Interests or Health Care?* During that hearing, one pharmacist testified to the problems caused by the PBMs' "outsized role":

The outsized role PBMs take in the pharmacy space has caused many problems for our patients and our practice. The three largest PBMs (Caremark owned by CVS Health which also owns Aetna, Express Scripts owned by Cigna, and Optum[] owned by UnitedHealthcare) control 80 percent of the market today, which means patients are forced by PBMs into using a certain pharmacy, often one owned and operated by the PBM, or they may be forced to get their drugs through the mail even though they want a pharmacist face-to-face in their community (See Exhibit A). Patients and their doctors have virtually no say in what drugs are used, since the PBM essentially forces which drugs can be

⁸⁷ *The Need to Make Insulin Affordable for All Americans*: Hearing Before the S. Comm. on Health, Education, Labor, & Pensions, 118th Cong. 12 (2023), <https://www.congress.gov/118/chrg/CHRG-118shrg54476/CHRG-118shrg54476.pdf>

⁸⁸ *Id.* at 101.

used – not because a drug is better or worse, but because the PBM can make more money from it.

PBMs contribute to artificially inflating drug costs using expensive name-brand medications when less expensive generic alternatives are available. To do this, PBMs claim that they secure large rebates from the manufacturer to bring the net cost of the product down to below the cost of the generic. Even if this were true (which would require complete transparency and a 100 percent pass-through of all monies that flow from a pharmaceutical manufacturer to a PBM), it does not negate the consumer harm that exists to patients when they are in the deductible phase and are paying more out of pocket for their medication costs. PBMs blame these formulary placements on plan sponsors, but plan sponsors like others in this industry are at the mercy of PBMs and their constant threats of rate hikes.

Another harmful, anticompetitive tactic employed by PBMs is spread pricing, which refers to the difference between how much a PBM reimburses the pharmacy for a drug and the higher price they turn around and charge the plan for the same prescription. For years, community pharmacists have said that PBMs have been playing spread pricing games, contributing to higher drug costs to the detriment of patients and the taxpayer-funded programs the PBMs are supposed to serve. Studies of multiple state Medicaid managed care programs have indicated that PBMs are overcharging taxpayers for their services in Medicaid managed care, reimbursing pharmacies low for medications dispensed, billing the state Medicaid program high for the cost of those medications, and retaining the difference, called “spread.”⁸⁹

239. A March 27, 2024 Office of the Inspector General audit of the American Postal Workers Union Health Plan’s Pharmacy Operations administered

⁸⁹ Written Testimony of Kevin J. Duane, PharmD, U.S. House Committee at 1-2, Before the H. Comm. on Energy & Com. Subcomm. on Oversight and Accountability, Investigations, Hearing on “The Role of Pharmacy Benefit Managers in Prescription Drug Markets Part I: Self-Interest or Health Care?” (May 23, 2023), <https://oversight.house.gov/wp-content/uploads/2023/05/Kevin-Duane-written-testimony-5.23.23.pdf>.

by Express Scripts between 2016 and 2021 concluded that Express Scripts overcharged the American Postal Workers Union and the Federal Employees Health Benefits Program (“FEHBP”) \$44,882,688 (including lost investment income) by: (1) failing to provide the FEHBP with pass-through transparent drug pricing for retail pharmacy claims, (2) failing to provide the FEHBP with several of the drug purchasing discounts collected by Express Scripts for drugs filled by its own mail order warehouses and specialty pharmacies, (3) failing to return certain retail pharmacy claim transaction fees it was credited for the American Postal Workers Union’s retail prescription drug benefits, (4) withholding from the FEHBP a portion of the drug manufacturing rebates it collected, and (5) erroneously withholding through its sister company, Ascent, a portion of the FEHBP’s manufacturer rebates in 2019 and 2020.⁹⁰

240. Further, on July 9, 2024, the FTC published an interim report as part of an ongoing study of “pharmacy benefit managers … and their impact on access to and affordability of medicines.”⁹¹

⁹⁰ Audit of the Am. Postal Workers Union Health Plan’s Pharmacy Operations as Administered by Express Scripts, Inc. for Contract Years 2016 through 2021, U.S. Office of Personnel Mgmt., Office of the Inspector General, (March 27, 2024), <https://oig.opm.gov/reports/audit/audit-american-postal-workers-union-health-plans-pharmacy-operations-administered-0>

⁹¹ *Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* at 1, Interim Staff Report, FTC (July 2024), https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf.

241. The report found that PBMs significantly influence what drugs are available to patients and at what price, which can lead to dire consequences where “nearly three in ten surveyed Americans reporting rationing or even skipping doses of their prescribed medicines due to high costs.”⁹² The FTC uncovered “troubling” evidence that “brand manufacturers and PBMs may be entering into rebate contracts designed to cut off access to generic and biosimilar competitors.”⁹³ In fact, it found “some rebate contracts explicitly premise high rebates on the exclusion of AB-rated generics.”⁹⁴

242. Notably, the FTC highlighted a brand drug manufacturer rebate agreement related to the Insulin Drug Lantus that shows:

[R]ebates premised on (1) preferred positioning over other competing products on a formulary or formulary tier (that is, the rebating manufacturer is one of several, one of few, or “1 of 1” in the competitive category); (2) “additional” rebates to specifically exclude competing manufacturers of competitive products from the formulary; and (3) “additional” rebates for implementing “brand step” requirements, meaning that patients must try and fail the preferred brand before being able to try the competing brand products.⁹⁵

⁹² *Id.*

⁹³ *Id.* at 66.

⁹⁴ *Id.* at 68.

⁹⁵ *Id.* at 67.

Figure 4: Rebate Agreement Regarding Lantus

A-4 Lantus and Lantus SoloSTAR						
REBATES FOR LANTUS® and LANTUS SoloSTAR® ¹ (INCLUDES ALL NDCs, STRENGTHS & PACKAGE SIZES)						
Formulary Type		1 of 1 Manufacturer Status**	1 of 2 Manufacturer Status**	1 of 3 Manufacturer Status**	1 of 4 Manufacturer Status	Listed Formulary Status
Non-Exclusion Formulary*	No Cost Share Differential	63.0%	58.0%	56.0%	N/A	N/A
	Cost Share Differential	63.0%	58.0%	56.0%	N/A	N/A
Exclusion Formulary*		63.0%	58.0%	56.0%	N/A	N/A
ACF / ACSF Closed Plans*		63.0%	58.0%	56.0%	N/A	N/A

*CVS/caremark Clients with sixty percent (60%) or more of their Plan lives that qualify for a higher Formulary Type Rebate rate shall earn the higher rate on all Client utilization. Clients that do not meet this threshold shall be evaluated on a Plan by Plan basis. Additionally, for clarity, open Plans (i.e. Plans which do not otherwise qualify as Closed Plans), will receive Closed Plan Rebate rates for any Competitive Category which qualifies as Closed.

¹ Plan must have all NDCs, strengths, package sizes of Lantus, Lantus SoloSTAR and Toujeo on the Preferred Brand Tier without restrictions to be eligible for this Rebate.

**Within the Long-Acting Insulin Category as defined in Section O.

INCREMENTAL ADDITIONAL BASE REBATE FOR ADOPTION OF EXCLUSIONS*:	
One Manufacturer of Competitive Products Excluded	2.0%
Two Manufacturers of Competitive Products Excluded	3.0%
Three Manufacturers of Competitive Products Excluded	N/A

*The incremental rebates above may be used for any current or future PBM exclusions. For avoidance of doubt, Incremental additional Base Rebate for adoption of Exclusions shall not apply to Non Preferred Brand Tier Status Rebates.

NON-PREFERRED BRAND TIER STATUS FOR LANTUS® and LANTUS SoloSTAR®	
N/A	

Incremental Additional Base Rebate For Adoption of Brand Step Therapy Program:	
Implementation of Brand Step Therapy Program**	2.0%

243. Highlighting that rebate structures between manufacturers and PBMs may “impede and impair competition and patient access to affordable medicines,” the report explained that such conduct warrants further scrutiny from the FTC, law enforcement, health plans, and policymakers for potential violations of Section 2(c) of the Robinson-Patman Act, among others.⁹⁶

⁹⁶ *Id.* at 66.

244. In the accompanying press release, FTC Chair Lina M. Khan announced, “[t]he FTC’s interim report lays out how dominant pharmacy benefit managers can hike the cost of drugs.”⁹⁷

245. A few weeks later, on July 23, 2024, the House Committee on Oversight and Accountability issued its own report and held a hearing on how the three largest PBMs (CVS Caremark, Express Scripts, and OptumRx) “inflate prescription drug costs and interfere with patient care for their own financial benefit.”⁹⁸ According to the report, PBMs “have also developed a business model where they can force drug manufacturers to pay high rebates for the manufacturer’s drug to be placed in a favorable formulary tier while excluding competing, lower-priced prescriptions such as cheaper generics.”⁹⁹ Coupled with other questionable conduct, these “tools allow PBMs to slow the market uptake of generics and biosimilar alternatives to brand-name drugs which serves to keep the cost of prescription drugs high.”¹⁰⁰ The House Report further found that while some decision to prefer brand medications “likely have valid clinical reasons, the sheer

⁹⁷ Press Release, *FTC Releases Interim Staff Report on Prescription Drug Middlemen*, FTC (July 9, 2024), <https://www.ftc.gov/news-events/news/press-releases/2024/07/ftc-releases-interim-staff-report-prescription-drug-middlemen>.

⁹⁸ Staff of H. Comm. on Oversight and Accountability, 118th Cong., Rep. on The Role of Pharmacy Benefit Managers in Prescription Drug Markets, House 3 (2024), <https://oversight.house.gov/wp-content/uploads/2024/07/PBM-Report-FINAL-with-Redactions.pdf> (“House Report”).

⁹⁹ *Id.* at 51.

¹⁰⁰ *Id.*

quantity and dramatic increase in costs highlight the priority of PBMs,” i.e., to “extract greater rebates from manufacturers” on “higher cost medications.”¹⁰¹

246. The House Report concluded that the PBMs “utilized opaque pricing and utilization schemes to overcharge plans and payers by hundreds of millions of dollars.”¹⁰² Such schemes include formulary manipulation and abuse, rebates to exclude biosimilars and other competition, and creation of foreign Rebate Aggregators in order to hide rebates and unearned fees.¹⁰³

247. At the hearing held on the same day the report was issued, the Committee pointed out that PBMs prioritize higher cost medications and that despite PBMs’ representations of cost reduction, cost of prescription drugs and spending on prescription medication have gone up every year.¹⁰⁴ And when PBM executives failed to provide clear answers to their questions, House Representatives were quick to admonish them for it.¹⁰⁵ For example, Representative Lisa McClain (R-Mich.) commented, “There lies your problem. I have been asking for data and you dive.

¹⁰¹ *Id.* at 31.

¹⁰² *Id.* at 4.

¹⁰³ See *Id.* at 27-35.

¹⁰⁴ Press Release, Hearing Wrap Up: Oversight Committee Exposes How PBMs Undermine Patient Health and Increase Drug Costs, H. Comm. on Oversight and Accountability (July 23, 2024), <https://oversight.house.gov/release/hearing-wrap-up-oversight-committee-exposes-how-pbms-undermine-patient-health-and-increase-drug-costs/>.

¹⁰⁵ See *id.*

You want zero transparency and we can see why,” when PBM executives failed to explain how PBMs benefit the pharmaceutical marketplace and patient care.¹⁰⁶

248. House Committee on Oversight and Accountability Chairman James Comer even followed up with letters to the chief executives of the PBM Defendants, citing relevant federal statutes on perjury, asking them “to correct the record for statements made during their appearance before the House Oversight Committee” that “contradict the Committee’s and the Federal Trade Commission’s findings about the PBMs’ self-benefitting practices that jeopardize patient care, undermine local pharmacies, and raise prescription drug prices.”¹⁰⁷

249. On September 20, 2024, the FTC formally brought suit against the PBM Defendants and their affiliated Rebate Aggregators “for engaging in anticompetitive and unfair rebating practices that have artificially inflated the list price of insulin drugs, impaired patients’ access to lower list price products, and shifted the cost of high insulin list prices to vulnerable patients.”¹⁰⁸

¹⁰⁶ See *id.*

¹⁰⁷ Press Release, *Chairman Comer Calls on PBM Executives to Correct Hearing Testimony*, H. Comm. on Oversight and Accountability (Aug. 28, 2024), <https://oversight.house.gov/release/chairman-comer-calls-on-pbm-executives-to-correct-hearing-testimony/>.

¹⁰⁸ Press Release, FTC Sues Prescription Drug Middlemen for Artificially Inflating Insulin Drug Prices, FTC (Sept. 20, 2024), <https://www.ftc.gov/news-events/news/press-releases/2024/09/ftc-sues-prescription-drug-middlemen-artificially-inflating-insulin-drug-prices>.

250. The FTC’s administrative complaint challenged the same conduct as described here, charging that the PBM Defendants “created a perverse drug rebate system that prioritizes high rebates from drug manufacturers, leading to artificially inflated insulin list prices” to the detriment of patients who need these life-saving medications.¹⁰⁹

251. Specifically, the FTC alleged that even though the PBM Defendants and Rebate Aggregator Defendants do not provide any additional service to the Manufacturer Defendants, they negotiate rebate and fee rates with the drug manufacturers, incentivized by the higher rebates and fees generated by insulin products with higher list prices.¹¹⁰ One Novo Nordisk Vice President even said that the PBMs were “addicted to rebates.”¹¹¹

252. According to the FTC complaint, even when lower list price insulins are available, the PBM Defendants excluded them in favor of identical high list price, highly rebated versions.¹¹² One Vice President at Optum said that this strategy “allowed the Big Three to continue to ‘drink down the tasty … rebates’ on high list price, highly rebated insulins.”¹¹³

¹⁰⁹ *Id.*

¹¹⁰ *Id.*

¹¹¹ *Id.*

¹¹² *Id.*

¹¹³ *Id.*

253. In a separate statement issued on the same day, the FTC Deputy Director Rahul Rao made clear that the FTC’s Bureau of Competition was also concerned about the active role played by the Manufacturer Defendants in the challenged conduct.¹¹⁴ He made clear that “all drug manufacturers should be on notice that their participation in the type of conduct challenged here can raise serious concerns, with a potential for significant consumer harm, and that the Bureau of Competition reserves the right to recommend naming drug manufacturers as defendants in any future enforcement actions over similar conduct.”¹¹⁵

H. While Government and Public Scrutiny Has Recently Forced Some Changes, Prices for Insulin Drugs Remain High from Defendants’ Scheme and Plaintiffs and Class Members Have Not Been Compensated for Their Damages

254. With scrutiny from both the Government and the public increasing in recent years, the Manufacturer Defendants recently announced limited pricing changes and certain out-of-pocket limits. Specifically, on March 1, 2023, Eli Lilly announced that it would cap the prices of certain insulin medications at \$35 per month, with additional reductions to follow later in the year. In its announcement, Eli Lilly asserted that beginning May 1, 2023, its Lispro injection would be listed at

¹¹⁴ Statement of FTC Bureau of Competition Deputy Director Rahul Rao on Lawsuit Against PBMs and the Role of Drug Manufacturers in Distorting Competition in the U.S. Drug Distribution System, FTC (Sept. 20, 2024), https://www.ftc.gov/system/files/ftc_gov/pdf/insulin-manufacturing-statement.pdf.

¹¹⁵ *Id.* at 2.

\$25 per vial effective, and that it would reduce the price of its Humalog and Humulin injections by 70% starting in the fourth quarter of 2023. Eli Lilly's recent choice to reduce prices for two diabetes medications suggests that, prior to this March 1, 2023 price reduction announcement, the prices of these medications were not raised to cover costs of research and development, manufacture, distribution, or any other necessary expense. Rather, it appears that the set price was arbitrarily increased and could have been reduced at any time.

255. Two weeks after Eli Lilly's price change announcement on March 14, 2023, Novo Nordisk similarly announced that it would lower the U.S. list prices of several insulin products by up to 75%. In particular, Novo Nordisk indicated that there would be new prices for its diabetes medications, Levemir, Novolin, NovoLog, and NovoLog Mix 70/30. Novo Nordisk will also reduce the list price of unbranded biologics to match the lowered price of each respective branded insulin. Currently, Novo Nordisk's price changes became effective on January 1, 2024, and, as with Eli Lilly's price reduction, suggest that the previous price increases for these medications were not to cover costs of research and development, manufacture, distribution, or any other necessary expense. Rather, once again, it appears that the set price was arbitrarily increased and could have been reduced at any time.

256. Importantly, these recent price changes (the "Price Cuts") are only prospective and do not in any way mitigate damages already incurred by TPPs like

Plaintiffs and Class members who paid for the Insulin Drugs based on the Manufacturer Defendants' artificial prices for years.

257. Moreover, the Price Cuts are limited to certain insulin medications, and do not encompass all Insulin Drugs. As part of their ongoing scheme to artificially increase prices for Insulin Drugs, PBMs provide preferred formulary placement to the most expensive diabetes medications based on list prices. Accordingly, it is plausible that the Manufacturer Defendants' and PBM Defendants' artificial pricing and kickback scheme will continue regardless of the Price Cuts, with the PBM Defendants continuing to target certain of the most expensive Insulin Drugs.

258. Further, these selective Price Cuts are woefully insufficient and even with the Price Cuts the prices for these lifesaving drugs remain unjustifiably high. Indeed, an Eli Lilly spokeswoman has represented that the current list price for a ten-milliliter vial of the fast-acting, mealtime insulin Humalog will drop to \$66.40 from \$274.70, and a ten-milliliter vial of Humulin will fall from \$148.70 to \$44.61.

259. Accordingly, the prices for these drugs still far exceed the Manufacturer Defendants' costs and remain significantly higher than prices for the same and similar drugs in other countries.

260. Moreover, in a move that undermines any benefit of some of the Price Cuts, on November 8, 2023, before the 65% price cut for its long-acting insulin Levemir had taken effect, Novo Nordisk announced that it would be discontinuing

Levemir in the United States, citing among other things, formulary-placement issues and “alternative treatments” for patients. Levemir is the only branded, long-acting insulin product for which Novo Nordisk announced a list price reduction and the only long-acting insulin FDA-approved for pregnancy. Yet, Novo Nordisk is discontinuing Levemir—before allowing the price reduction to take effect—with supply disruptions beginning in early 2024, followed by formal discontinuation of the Levemir FlexPen vial by the end of 2024.

261. Additionally, facing mounting political and public outcry over its artificial pricing scheme, Defendants have taken steps on Capitol Hill and in the public relations space to ensure their scheme can continue.

262. First, in response to public criticism, Defendants have increased their spending to spread their influence in Washington D.C. For example, in recent years Novo Nordisk’s political action committee (“PAC”) has doubled its spending on federal campaign donations and lobbying efforts. In fact, in 2017 alone, Novo Nordisk spent \$3.2 million lobbying Congress and federal agencies, which (at that point) was its biggest ever investment in directly influencing U.S. policymakers. By 2023, that number had risen to over \$5.1 million. Further, Eli Lilly and Sanofi also have contributed millions of dollars through their PACs in recent years. In 2023, Eli Lilly spent over \$8.4 million in lobbying and Sanofi spent over \$5.4 million.

263. Second, Defendants have recently begun publicizing programs ostensibly aimed at lowering the cost of insulins. These so-called affordability measures fail to address the structural issues that caused the price hikes. Rather, these are public relations measures that do not actually put an end to practices that have resulted in artificially inflated prices for the Insulin Drugs.

264. For example, in March 2019, Defendant Eli Lilly announced that it would produce an authorized generic version of Humalog, “Insulin Lispro,” and promised that it would “work quickly with supply chain partners to make [the authorized generic] available in pharmacies as quickly as possible.”

265. Eli Lilly testified to the Senate Finance Committee that “we can provide a lower-priced insulin more quickly without disrupting access to branded Humalog, on which thousands of insured patients depend and which will remain available for people who want to continue accessing it through their current insurance plans.”¹¹⁶

266. When it launched Lispro, its press release said the drug was the “same molecule” as Humalog, yet would be sold at half the price of Humalog. Eli Lilly expressly said it was to help make insulin medications “more affordable.”¹¹⁷

¹¹⁶ Staff of S. Comm. on Fin, 116th Cong., Rep. on Insulin; Letter from Joseph B. Kelley, Eli Lilly Vice President, Glob. Gov’t Affairs, to Charles E. Grassley & Ron Wyden at 2, S. Fin. Comm. (Mar. 8, 2019), https://www.finance.senate.gov/imo/media/doc/Eli%20Lilly_Redacted%20v1.pdf.

¹¹⁷ Press Release, *Lilly to Introduce Lower-Priced Insulin*, Eli Lilly & Co. (Mar. 4, 2019), <https://investor.lilly.com/node/40881/pdf>.

267. What Eli Lilly did not mention in its testimony to the Committee and statements to the public was that its rebate deals with the PBMs incentivized them to exclude Lispro from their formularies. For example, even though Lispro at \$137.50 would be available at half the price of Humalog, which remained on-formulary, Express Scripts' exclusion list for 2019¹¹⁸ specifically blocked it from its formulary.¹¹⁹

268. Likewise, in the months after Eli Lilly's announcement, reports raised questions about the availability of "Insulin Lispro" in local pharmacies. Following these news reports, the staff of the Offices of U.S. Senators Elizabeth Warren and Richard Blumenthal prepared a report examining the availability of this drug. The investigative report, *Inaccessible Insulin: The Broken Promise of Eli Lilly's Authorized Generic*, concluded that Eli Lilly's lower-priced, authorized generic insulin is widely unavailable in pharmacies across the country, and that the company has not taken meaningful steps to increase insulin accessibility and affordability.¹²⁰

¹¹⁸ See 2019 National Preferred Formulary Exclusions, Express Scripts (Nov. 15, 2019), https://www.express-scripts.com/art/pdf/Preferred_Drug_List_Exclusions_2019.pdf.

¹¹⁹ Bob Herman, *Express Scripts Won't Cover Eli Lilly's New Generic Insulin*, Axios (Apr. 26, 2019), <https://wwwaxios.com/2019/04/26/express-scripts-wont-cover-eli-lilly-insulin-lispro>.

¹²⁰ Sen. Elizabeth Warren & Sen. Richard Blumenthal, *Inaccessible Insulin: The Broken Promise of Eli Lilly's Authorized Generic*, (Dec. 2019), <https://www.warren.senate.gov/imo/media/doc/Inaccessible%20Insulin%20report.pdf>.

269. While Eli Lilly ultimately lowered the price of Lispro by 40% effective January 1, 2022, as of January 2023, Lispro did not appear on CVS Caremark's formulary and Humalog had been removed. The January 2023 formularies for Express Scripts and OptumRx expressly excluded Lispro.

270. In 2019, Novo Nordisk partnered with Walmart to offer ReliOn brand insulins for a discounted price at Walmart. However, experts have warned that the Walmart/Novo Nordisk insulins are not substitutes for most diabetics' regular insulins and should only be used in an emergency or when traveling. Importantly, for many diabetics, especially Type 1 diabetics, these insulins can be dangerous. ReliOn is not included on any of the PBM Defendants' formularies as of January 2023.

271. Thus, Defendants' "lower priced" insulin campaigns have not addressed the problem and the PBMs continue to exclude drugs with lower list prices despite their assurances of cost-savings for TPPs and beneficiaries.

V. INSULIN DRUGS

A. Diabetes: The Disease and Demographics

272. Diabetes is an epidemic in the United States. One in five health care dollars is spent caring for people with diagnosed diabetes. As of 2022, an estimated 37.3 million people in the United States—11.3% of the population—were living with Type 1 or Type 2 diabetes. A life-threatening disease, many of those living with

diabetes rely on daily insulin treatments to survive. Interruptions to these regimes can have severe consequences, including sustained damage to the kidneys, heart, nerves, eyes, feet, and skin. Indeed, diabetes is the leading cause of kidney failure, adult-onset blindness, and lower-limb amputations in the United States. Missed or inadequate insulin therapy can leave diabetics with too little insulin in their system, triggering hyperglycemia and then diabetic ketoacidosis. Left untreated, diabetic ketoacidosis can lead to loss of consciousness and death within days. Diabetic ketoacidosis is responsible for more than 500,000 hospital days per year at an estimated annual direct medical expense and indirect cost of \$2.4 billion.¹²¹

273. The number of Americans who live with diabetes has exploded in the last half century. In 1958, only 1.6 million people in the United States had diabetes. By the turn of the century, that number had grown to over 10 million. Just 14 years later, the head count tripled again. Now an estimated 37.3 million people in the United States—11.3% of the population—are living with diabetes. And this trend does not appear to be slowing: 86 million Americans have prediabetes, a health condition that significantly increases a person’s risk of Type 2 diabetes.

274. Diabetes occurs when a person has too much glucose—sugar—in their blood stream. Normally, the human body breaks down ingested food into glucose,

¹²¹ Abbas E. Kitabchi, et al., *Hyperglycemic Crises in Adult Patients with Diabetes*, 32 Diabetes Care 1335, 1335 (2009).

which in turn feeds cells and enables them to function. In this process, insulin functions as a key, opening the cells and permitting glucose to enter. A lack of insulin or responsiveness to insulin causes the process to break down. Glucose is unable to enter the cells, which leads to high blood sugar levels. Unchecked, high blood sugar levels in a non-diabetic can lead to Type 2 diabetes.

275. There are two basic types of diabetes. Roughly 90-95% of Americans living with diabetes developed the disease because they do not produce enough insulin or have become resistant to the insulin their bodies do produce. Known as Type 2, this more common form of diabetes is typically associated with increased body weight and is often developed later in life. When first diagnosed, many Type 2 patients can initially be treated with tablets that help their bodies either secrete more insulin or better respond to the insulin they already produce. Nonetheless, these tablets are often insufficient for patients in the long term. To adequately control their blood sugar levels, many Type 2 patients must inject insulin to supplement that which their bodies produce. About a quarter of Type 2 patients rely on insulin treatment.

276. Type 1 diabetes occurs when a patient completely ceases insulin production. This form of diabetes is usually diagnosed in children and young adults, but can occur at any age. In contrast to Type 2 patients, people with Type 1 diabetes do not produce any insulin and, without regular injections of insulin, they will die.

Individuals living with Type 1 must rely on insulin treatments from the point of diagnosis until death.

277. If left untreated or under-treated, diabetes can become a debilitating and deadly disease. Indeed, it remains the seventh leading cause of death in the United States, despite the availability of effective treatment. People with diabetes are almost twice as likely to have heart disease or a heart attack and one and one-half times more likely to have a stroke than those without the disease. Chronic kidney disease and failure is also much more common among those with diabetes. Furthermore, diabetes damages blood vessels and nerves, leading to serious, hard-to-treat infections, and even amputations. Finally, the disease is the leading cause of blindness.

278. The explosion in diabetes prevalence has hit minorities and the poor the hardest. Type 2 diabetes disproportionately impacts African-Americans, American Indians, Asian Americans, Hispanics/Latinos, and Pacific Islanders. For example, Native Americans are 420% more likely to die from diabetes-related causes of death than other Americans. With decreased access to nutritious food sources and fitness options, low-income individuals are at a greater risk of obesity and, correspondingly, diabetes. These same demographic groups also account for a disproportionate share of the uninsured.

B. The Origins of Insulin Treatment

279. Despite its potentially deadly impact, diabetes is a highly treatable illness. For patients who are able to follow a prescribed treatment plan consistently, the harmful symptoms and health complications associated with the disease are entirely avoidable. And what's more, unlike many high-burden diseases, treatment for diabetes has been available for almost a century.

280. In 1922, two men pioneered a technique for removing active insulin from an animal pancreas that could then be used to treat human patients with diabetes.

281. A “widely celebrated tale of biomedical serendipity,”¹²² this breakthrough is revered for two reasons. First, the duo that discovered how to extract insulin for patient treatment was an unlikely pair: a young orthopedic surgeon without laboratory training, Frederick Banting, and his medical-student assistant, Charles Best. Second, neither Banting nor Best applied for a patent on their game-changing innovation because they wanted to ensure their discovery remained open to the public, available to all. This decision offers a sad commentary on the state of the current pharmaceutical industry.

¹²² Jeremy A. Greene & Kevin R. Riggs, *Why Is There No Generic Insulin? Historical Origins of a Modern Problem*, 372 N. Eng. J. Med. 1171, 1171 (2015).

282. Ironically, Banting and Best eventually ended up applying for a patent to guarantee access: Banting and Best realized that if they did not patent their drug, someone else would. To prevent others from obtaining exclusive rights and restricting supply, Banting and Best obtained a patent and then sold it to the University of Toronto for \$1 each. As they wrote to the University's president, the patent was a form of publication: "When the details of the method of preparation are published anyone would be free to prepare the extract, but no one could secure a profitable monopoly."¹²³

283. After selling their patent to the University of Toronto, university researchers attempted to manufacture insulin on campus. However, they quickly realized they lacked the facilities necessary to meet the demand. Therefore, to scale production, the University of Toronto teamed up with Eli Lilly, "an established pharmaceutical company with experience producing glandular extracts."¹²⁴ Under this arrangement, Eli Lilly was allowed to apply for U.S. patents on any improvements to the manufacturing process. In addition to their contract with Eli Lilly, the Toronto team licensed the rights to produce insulin to a few other companies, including Denmark's Nordisk Insulin Laboratorium and Novo

¹²³ M. Bliss, *The Discovery of Insulin* (2013).

¹²⁴ Jeremy A. Greene & Kevin R. Riggs, *Why Is There No Generic Insulin? Historical Origins of a Modern Problem*, 372 N. Eng. J. Med. 1171, 1171 (2015).

Terapeutisk Laboratorium.¹²⁵ Those initial licenses laid the groundwork for Eli Lilly and Novo Nordisk's future domination over the sale of insulin products.

284. Although the Toronto team's early iteration of insulin was immediately perceived as "a lifesaving drug of vast clinical public health significance,"¹²⁶ subsequent research led to further improvements in the drug's efficacy. The original animal insulin isolated by the Toronto team was short-acting—it only had an effect on patient blood sugar levels for three to six hours. In the early 1930s, scientists at Nordisk discovered that the addition of a certain protein to insulin altered its absorption into the blood stream, prolonging its effect. This form of insulin became known as long-acting. A subsequent innovation in 1946—the addition of zinc to form the crystalline protamine-isophane insulin, now known as neutral protamine Hagedorn (NPH)—made it possible to combine long-acting and rapid-acting insulin. This advancement allowed many diabetes patients to take a single daily injection. Soon afterward, a method for prolonging the action of insulin without adding protamine was discovered. These developments offered new options for the dosing of insulin, but they also extended the reach of insulin patents into the 1970s.

285. When the animal-based insulin patents finally began to expire, researchers took another step forward in the development of insulin technology. In

¹²⁵ Nordisk and Novo merged in 1989 to form Novo Nordisk.

¹²⁶ Jeremy A. Greene & Kevin R. Riggs, *Why Is There No Generic Insulin? Historical Origins of a Modern Problem*, 372 N. Eng. J. Med. 1171, 1172 (2015).

the late 1970s, scientists began to produce human insulin through recombinant technology. By 1982, Eli Lilly brought the first recombinant human insulins—Humulin R (regular) and N (NPH)—to the U.S. marketplace. Around the same time, Novo and Nordisk developed methods for chemically converting bovine insulin into human insulin. In 1988, a year prior to merging, Novo and Nordisk obtained approval for their own recombinant insulin. This innovation allowed them to continue shared domination over insulin sales with Eli Lilly. It also enabled Eli Lilly and Novo Nordisk to spin a fresh web of insulin patents, promising to stretch into the 21st century.

286. After the introduction of human insulin, an improved understanding of the human genetic code and recombinant technology put a third insulin development within reach. In the mid-1980s, scientists began to modify the molecular structure of insulin, attempting to improve its physiological effects. By 1996, Eli Lilly had obtained approval for Humalog (generic name, insulin lispro), the first rapid-acting, man-made insulin. This new type of insulin—known as an analog—allowed for faster absorption times. Never far behind, Novo Nordisk released its own rapid-acting analog, Novolog (generic name, insulin aspart), in 2000. Four years after that, a third pharmaceutical company, Sanofi, released another rapid-acting analog, Apidra (generic name, insulin glulisine).

287. The same technological advances that brought about rapid-acting analogs gave rise to long-acting analogs. In 2000, Sanofi released the first long-acting analog. This drug was branded as Lantus (generic name, insulin glargine). Five years later, Novo Nordisk gained approval for its own long-acting analog, Levemir (generic name, insulin detemir). The first patents on these long-acting analogs expired in June 2014, nearly a century after Banting and Best's first patent application in 1923.

288. In February 2015, Sanofi launched a higher dosage of insulin glargine, branded as Toujeo (generic name, insulin glargine). In September 2015, Novo Nordisk released a fourth type of long-acting insulin called Tresiba (generic name, insulin degludec). In December 2016, Eli Lilly released its own version of insulin glargine, branded as Basaglar (generic name, insulin glargine). Basaglar is a follow-on product to Lantus.¹²⁷

289. In September 2017, Novo Nordisk released a fourth rapid-acting insulin called Fiasp (generic name, insulin aspart). Fiasp is a slightly modified version of Novolog.

¹²⁷ It is not considered a generic drug because it did not rely on the Food, Drug, and Cosmetic Act's (FDCA) Abbreviated New Drug Application pathway—the normal pathway to generic entry—for approval. Instead, Basaglar was approved through a different FDCA pathway as a follow-on medication.

C. Insulin Treatment Landscape

290. Today, analogs dominate insulin sales. Doctors and patients prefer analogs because they more closely mimic the way the human body naturally absorbs insulin released by the pancreas. As a result, it can be used in more flexible ways.

291. The American Diabetes Association—the organization responsible for setting guidelines for diabetes care in the United States—recommends analogs for treatment of individuals with both Type 1 and Type 2 diabetes.

292. Due to the advantages of analog insulin, analog insulin dominates the insulin markets for both long-acting analog insulins and rapid-acting analog insulins, and sales of natural human insulin products, such as Novo Nordisk's Novolin and Eli Lilly's Humulin, have dropped drastically.

293. In 2016, the top three selling insulins were all analogs: Sanofi's long-acting Lantus garnered \$6.98 billion in sales; Novo Nordisk's long-acting Novolog: \$3.03 billion; and Eli Lilly's rapid-acting Humalog: \$2.84 billion.

294. Table 1 summarizes the Insulin Drugs at issue.

Table 1: Insulin Available in the United States					
Insulin Type	Action	Brand Name	Generic Name	Company	FDA Approval
Human	Short-acting	Humulin R	Insulin Regular	Eli Lilly	1982
		Novolin R	Insulin Regular	Novo Nordisk	1991

Table 1: Insulin Available in the United States					
Insulin Type	Action	Brand Name	Generic Name	Company	FDA Approval
	Intermediate Acting	Humulin N	Insulin Suspension Isophane (NPH)	Eli Lilly	1982
		Novolin N	Insulin Suspension Isophane (NPH)	Novo Nordisk	1991
Analogs	Rapid-Acting	Humalog	Lispro	Eli Lilly	1996
		Novolog	Aspart	Novo Nordisk	2000
		Apidra	Glulisine	Sanofi	2004
		Fiasp	Aspart	Novo Nordisk	2017
	Long-Acting	Lantus	Glargine	Sanofi	2000
		Levemir	Detemir	Novo Nordisk	2005
		Basaglar	Glargine	Eli Lilly	2016
		Toujeo	Glargine	Sanofi	2015
		Tresiba	Insulin Degludec	Novo Nordisk	2016

D. Climbing Insulin List Prices

295. Despite the availability of many highly effective insulins, too many people living with diabetes go without proper treatment for a familiar reason: cost.

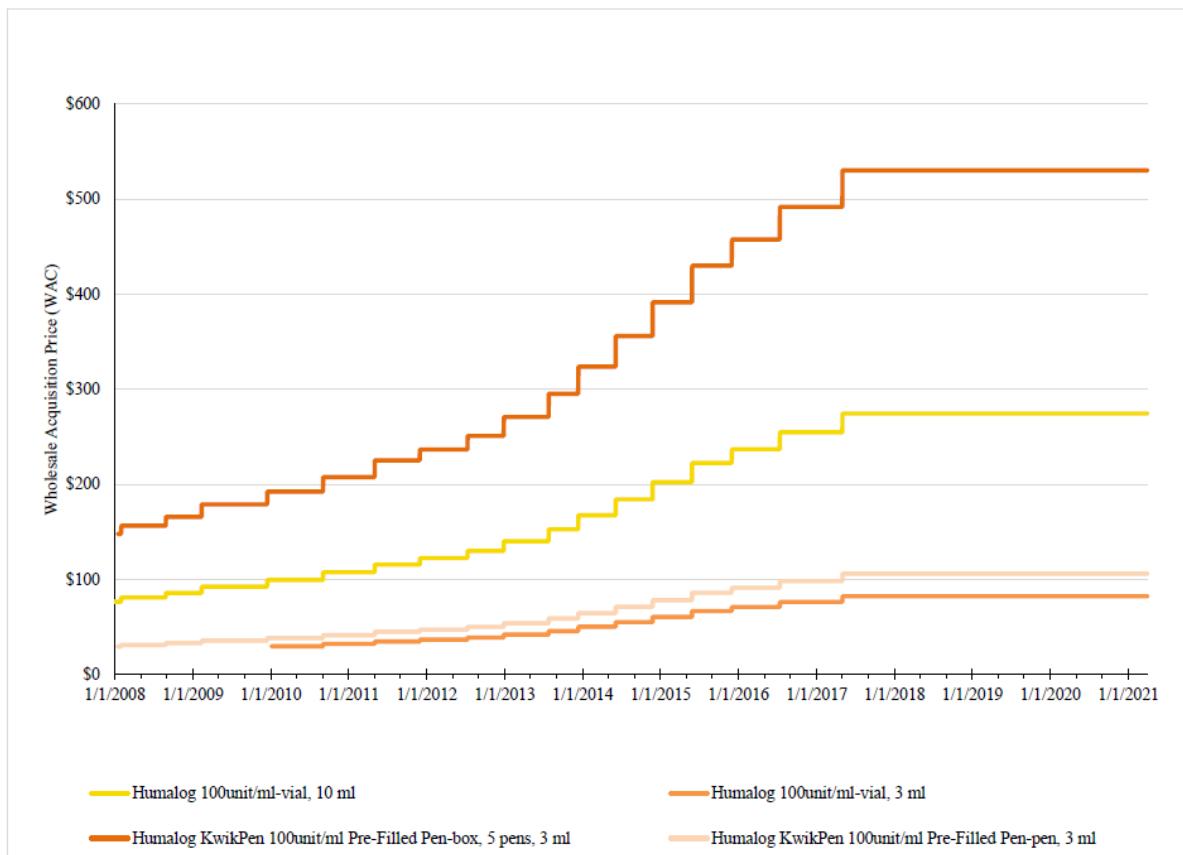
296. As time goes on, the cost to produce the Insulin Drugs has gone down, while, paradoxically, the amount people pay for the drugs has gone up. A September

2018 study in BMJ Global Health calculated that, based on production costs, a reasonable and profitable price for a one-year supply of human insulin is between \$48 and \$71 per person and between \$78 and \$133 for analog insulin.¹²⁸ Another study, based on data collected through 2023, concluded that sustainable cost-based prices “for treatment with insulin in a reusable pen device could cost as little as \$96 (human insulin) or \$111 (insulin analogues) per year for a basal-bolus regimen, \$61 per year using twice-daily injections of mixed human insulin, and \$50 (human insulin) or \$72 (insulin analogues) per year for a once-daily basal insulin.”¹²⁹

297. Eli Lilly raised the list price of Humulin from \$165 in 1997 to \$1,784 in 2021, over a ten-fold increase. Eli Lilly raised the list prices of Humalog to \$530.40 for a package of pens and \$510.45 for a box of cartridges by the end of 2017. Eli Lilly also raised the list prices of Basaglar to \$326.36 for a package of pens by the end of 2017. Figure 5 demonstrates Eli Lilly’s price increases from 2006 to 2019 for Humalog.

¹²⁸ Gotham D, Barber MJ, Hill A., Production costs and potential prices for biosimilars of human insulin and insulin analogues. *BMJ GLOBAL HEALTH* 2018;3:e000850.

¹²⁹ Melissa J. Barber, et al., *Estimated Sustainable Cost-Based Prices for Diabetes Medicines*, JAMA NETWORK: OPEN (Mar. 27, 2024).

Figure 5: Rising list prices of Humalog vials and pens from 2008-2021

298. Novo Nordisk's list prices for Levemir were \$403.50 for a package of pens at the end of 2017 and \$293.75 for a vial at the end of 2018. Novo Nordisk's list prices for Novolog sat at \$558.83 for a package of pens and \$289.36 for a vial at the end of 2018. Novo Nordisk's list prices for Fiasp also sat at \$558.83 for a package of pens and \$289.36 for a vial at the end of 2018. Novo Nordisk's list price for Tresiba was \$484.68 for a package of pens at the end of 2018. Most diabetes patients need at least one package of insulin per month. Figures 6 and 7 demonstrate Novo Nordisk's price increases from 2006 to 2021 for Levemir and Novolog. And Figures 8 and 9 show Novo Nordisk's list price increases for Tresiba and Fiasp.

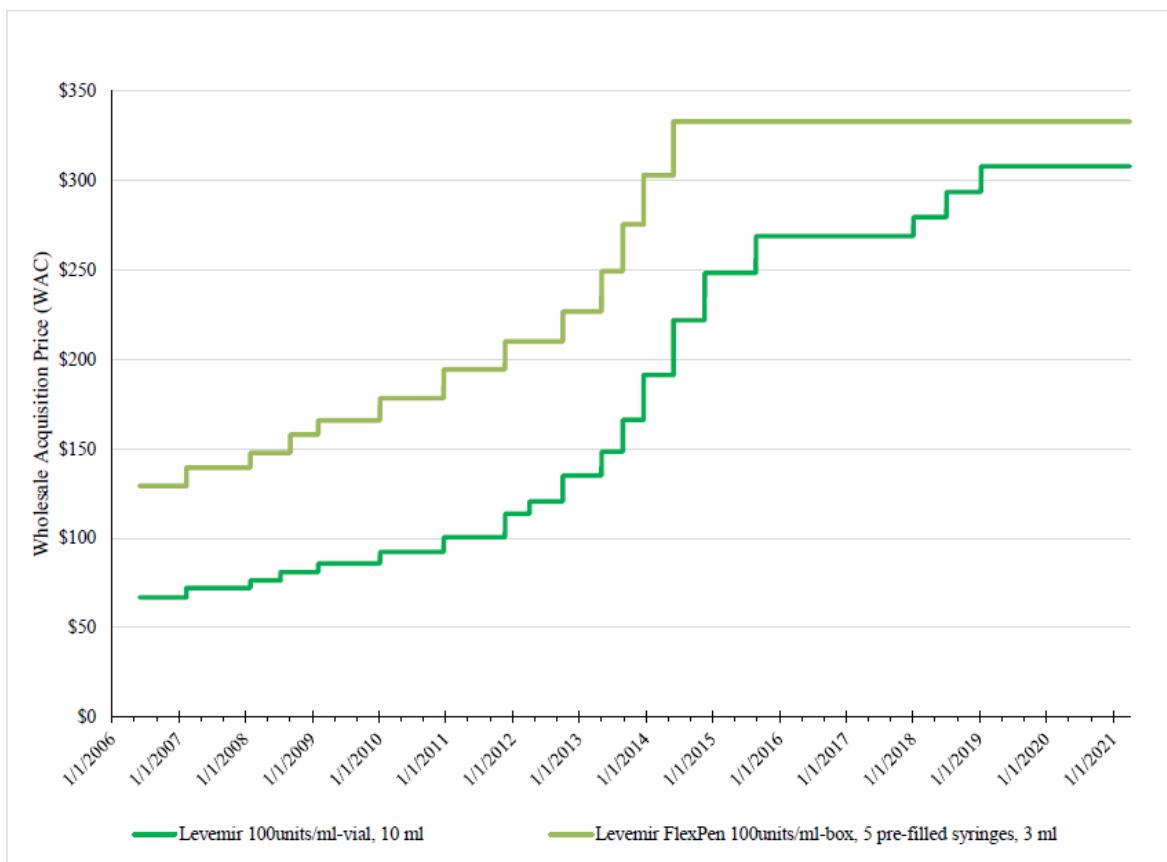
Figure 6: Rising list prices of Levemir vials and pens from 2006-2021

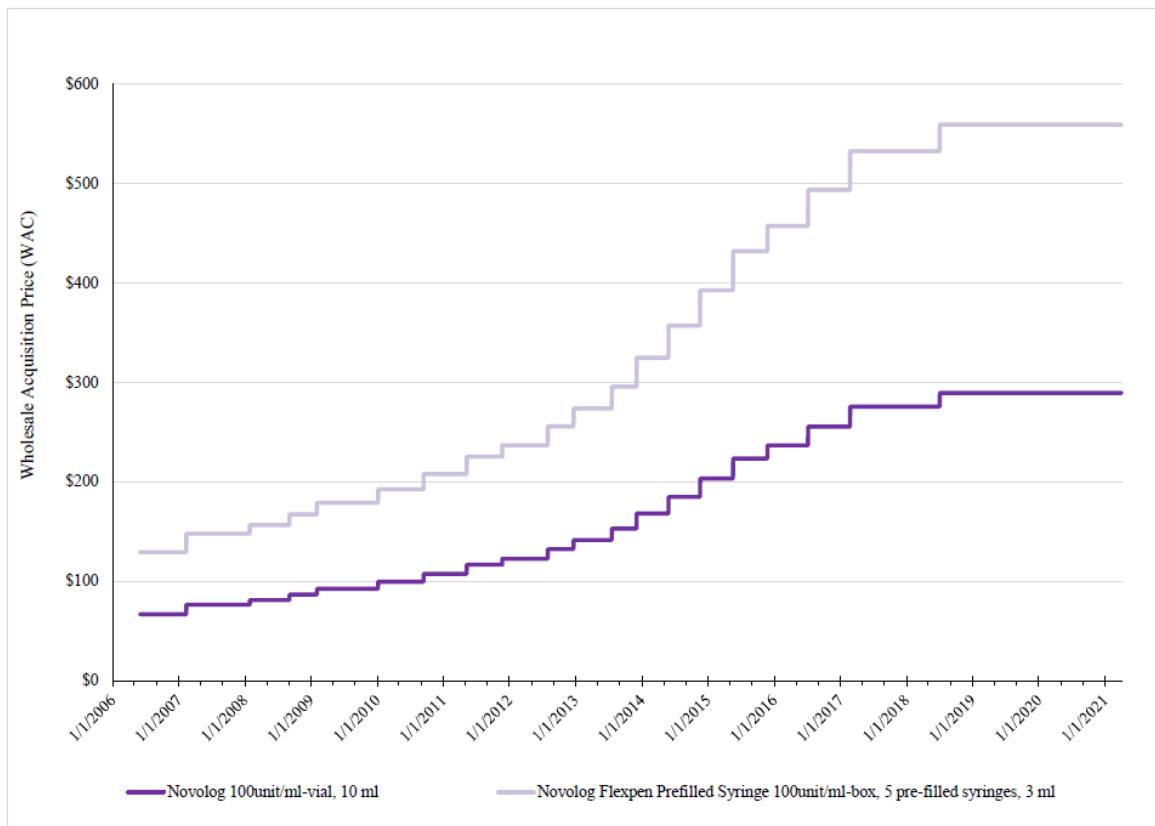
Figure 7: Rising list prices of Novolog vials and pens from 2006-2021

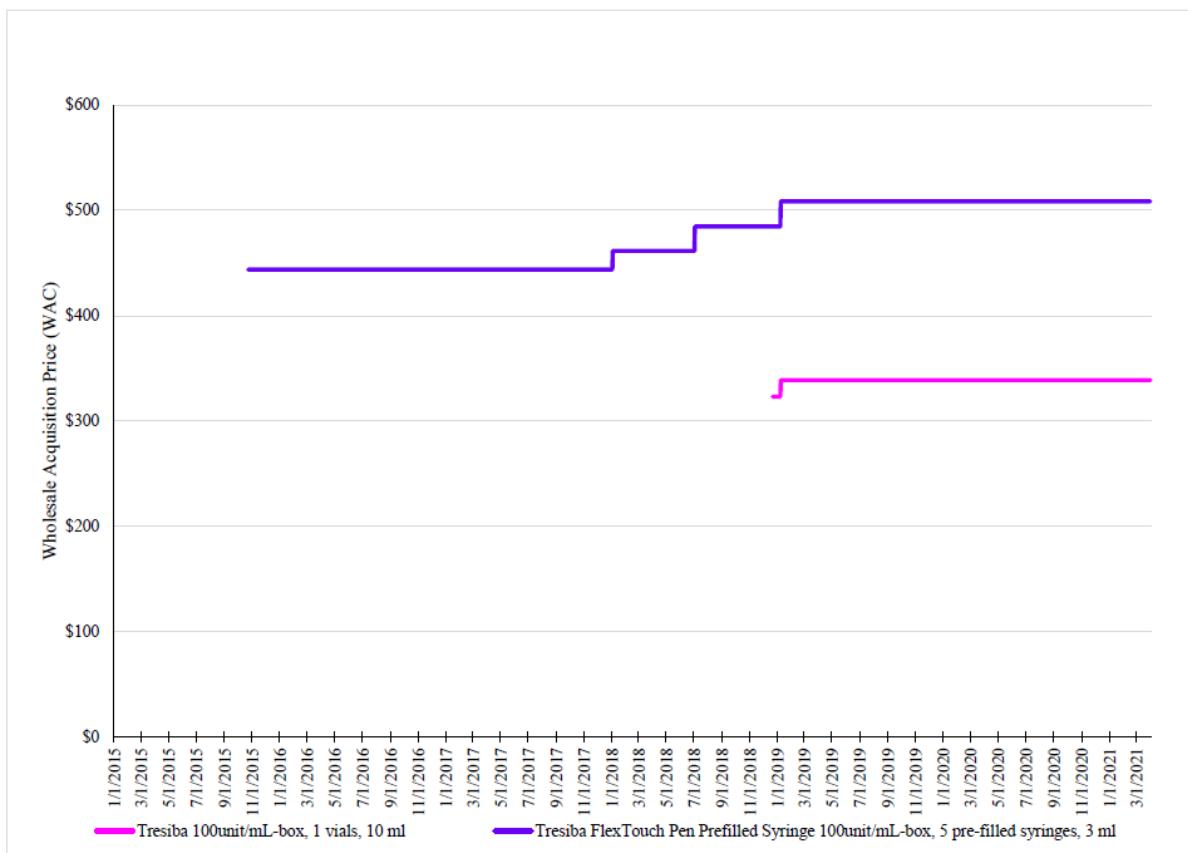
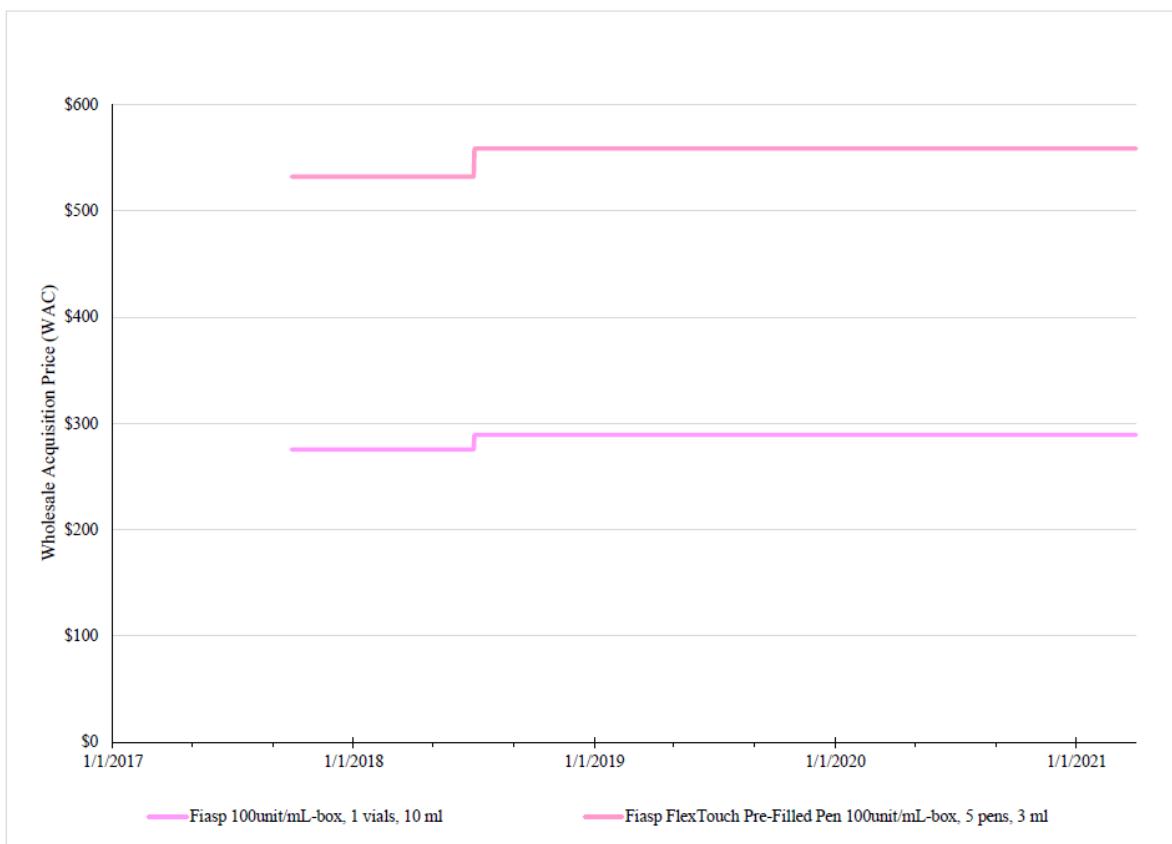
Figure 8: Rising list prices of Tresiba vials and pens from 2015-2021

Figure 9: Rising list prices of Fiasp vials and pens from 2017-2021

299. Sanofi's list prices for Lantus, the top-selling analog insulin, sat at \$404.29 for a package of pens and \$269.54 for a vial at the end of 2018. Sanofi's list prices for Apidra were \$521.41 for a package of pens and \$269.91 for a vial at the end of 2018. Sanofi's list price for Toujeo was \$620.57 for a package of Toujeo pens at the end of 2018. Figures 10 and 11 demonstrate Sanofi's price increases from 2006 to 2021 for Lantus and Apidra vial and pen packages. Figure 12 demonstrates Sanofi's list prices increases for Toujeo.

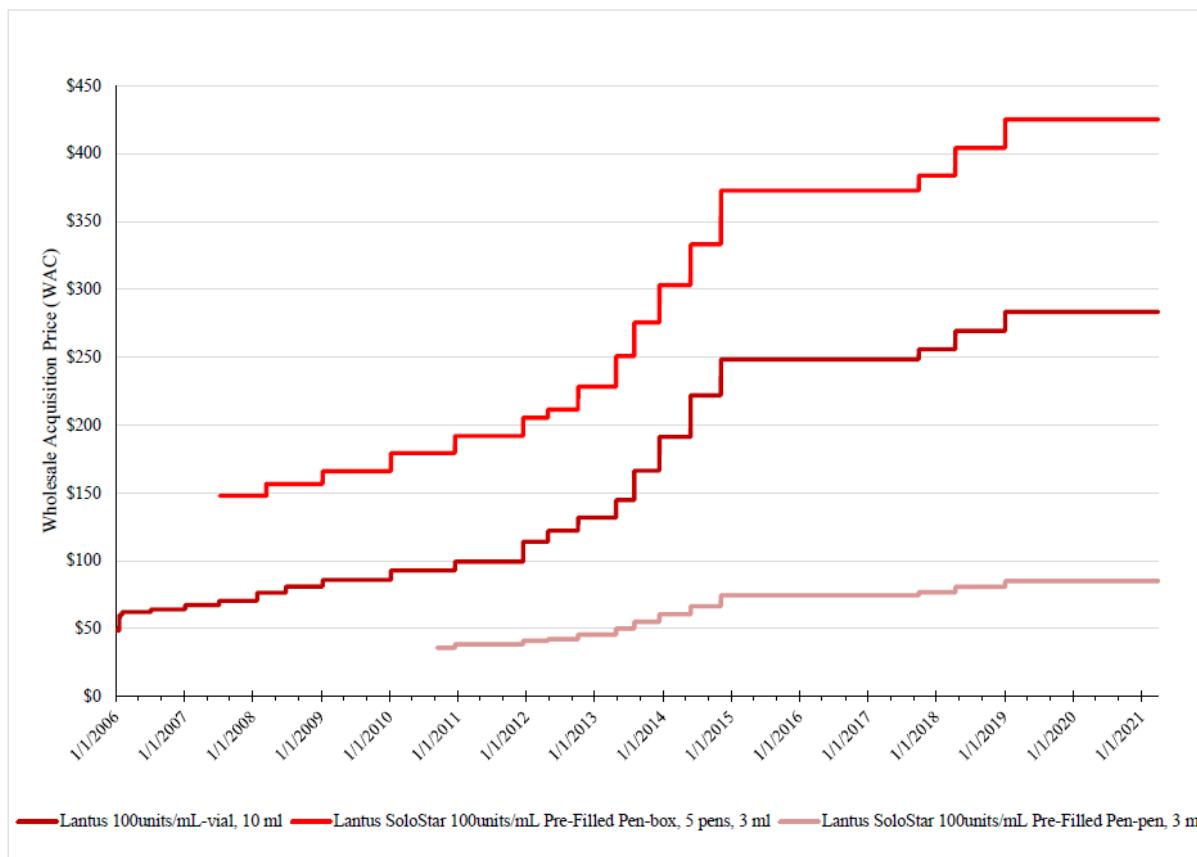
Figure 10: Rising list prices of Lantus vials and pens from 2006-2021

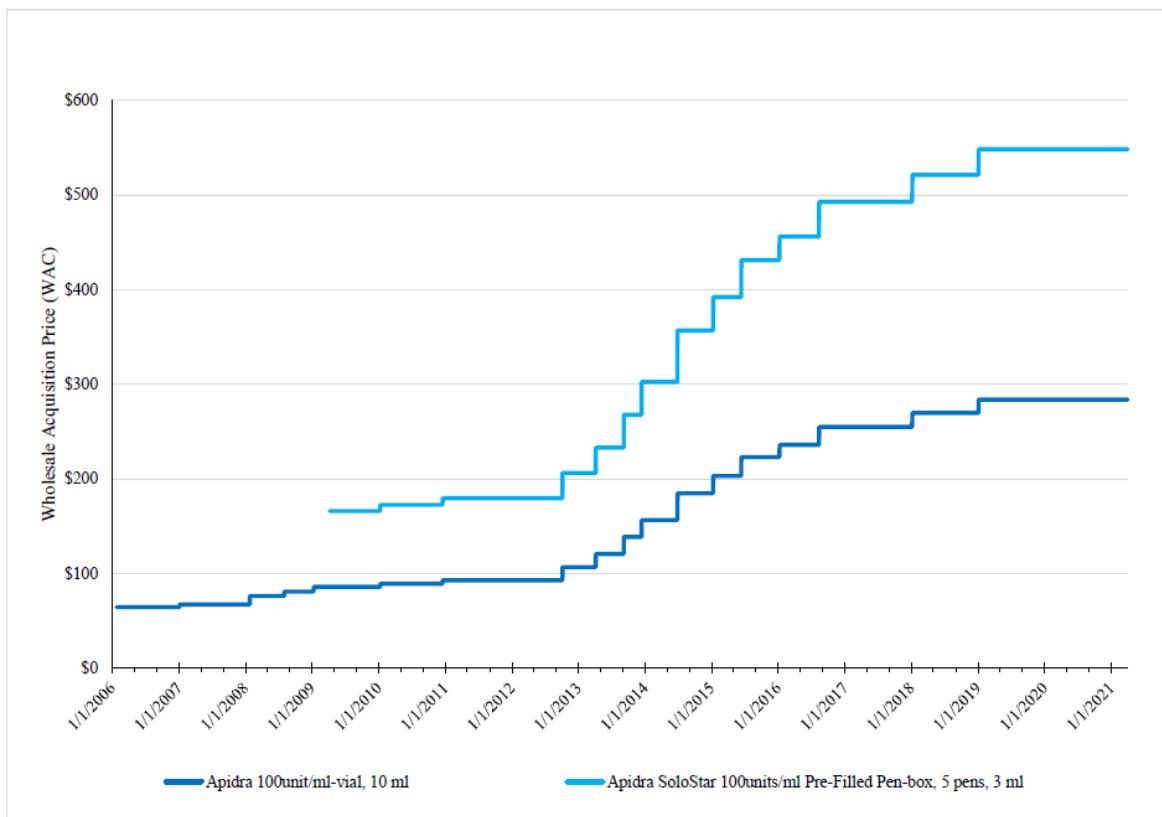
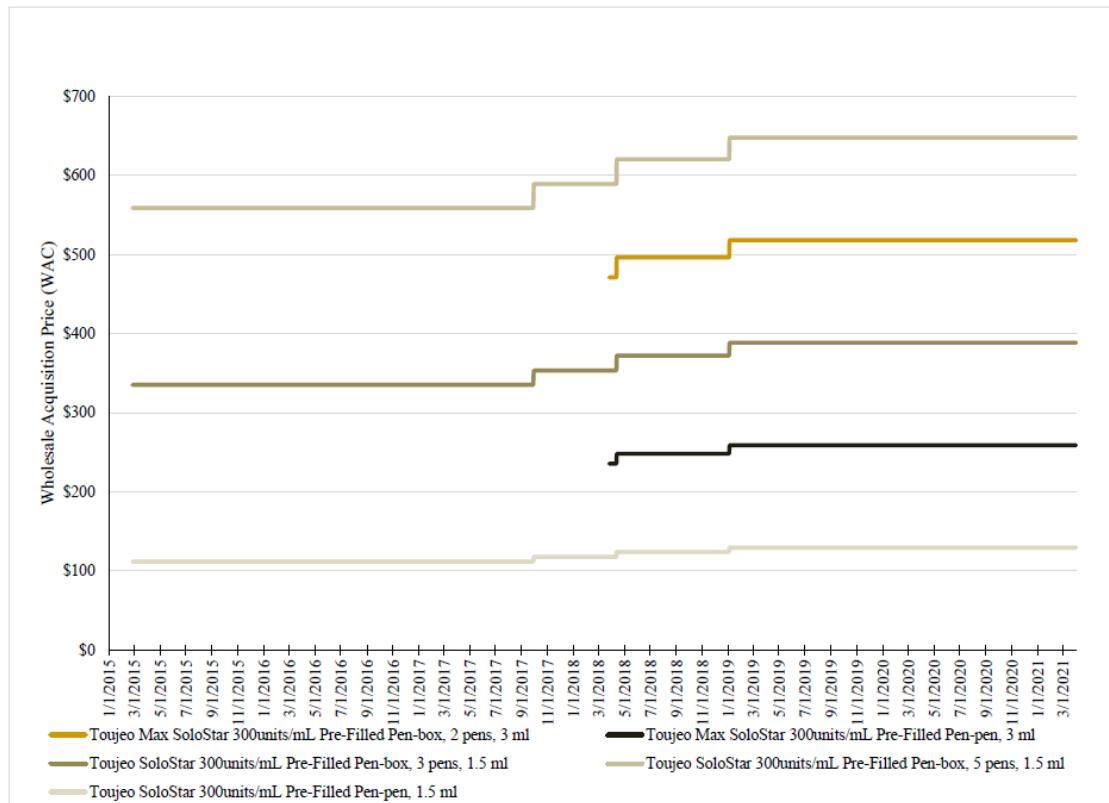
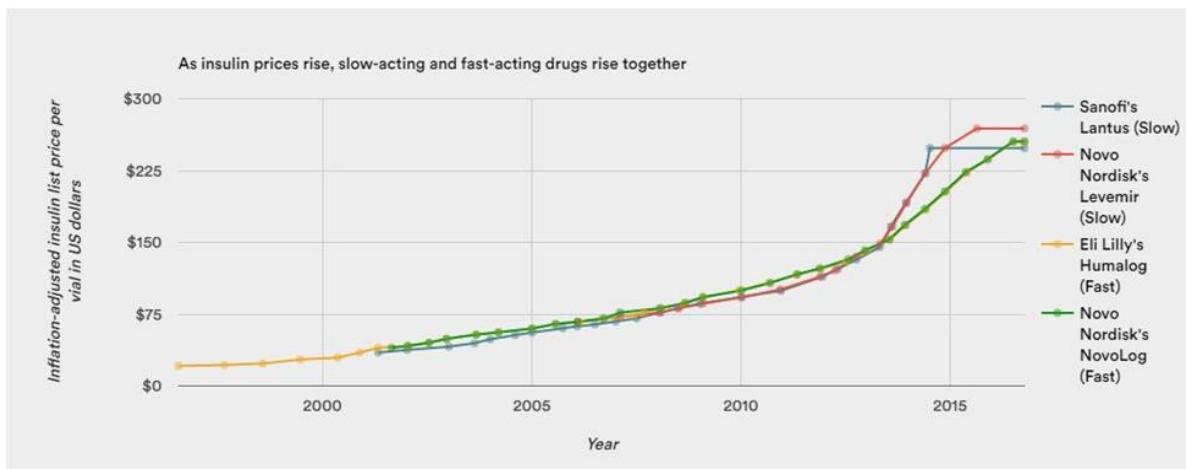
Figure 11: Rising list prices of Apidra vials and pens from 2006-2021

Figure 12: Rising list prices of Toujeo pens from 2015-2021

300. The list prices of Insulin Drugs have not always been so high. In just the last five years, Sanofi and Novo Nordisk have raised Lantus's and Levemir's reported prices an astounding 168% and 169%, respectively. In fact, in 2016, Novo Nordisk and Sanofi were responsible for the highest drug list price increases in the *entire pharmaceutical industry*. This distinction largely reflected their price hikes for Lantus and Levemir. Figure 13 shows Eli Lilly, Novo Nordisk, and Sanofi's exponential list price hikes from 2000 to 2015.

Figure 13: Rising insulin list prices from 2000-2015¹³⁰



301. Eli Lilly, Novo Nordisk, and Sanofi have not only dramatically increased their insulins' list prices in the last 15 years, they have done so in perfect lockstep. In thirteen instances since 2009, Sanofi and Novo Nordisk raised the list prices of their long-acting analog insulins, Lantus and Levemir, in tandem, "taking the same price increase down to the decimal point within a few days of each other."¹³¹ As one healthcare analyst put it: "That is pretty much a clear signal that your competitor doesn't intend to price-compete with you."¹³² Eli Lilly, Novo Nordisk, and Sanofi have engaged in the same lockstep behavior with respect to their rapid-acting analog insulins, Humalog, Novolog, and Apidra, respectively.

¹³⁰ Rebecca Robbins, *The Insulin Market is Heading for a Shakeup. But Patients May Not Benefit*, STAT (Oct. 14, 2016), <https://www.statnews.com/2016/10/14/insulin-prices-generics/>.

¹³¹ Robert Langreth, Hot Drugs Show Sharp Price Hikes in Shadow Market, Bloomberg (May 6, 2015).

¹³² *Id.*

302. An example from 2014 demonstrates this behavior and shows how Defendants inflated their list prices in ways that were completely untethered from their insulins' efficacy, value, or production costs. In May 2014, Novo Nordisk's U.S. Pricing Committee (PC) discussed how to respond to Sanofi's recent pricing actions. Farruq Jafery of Novo Nordisk emailed the rest of the pricing committee, stating "Sanofi took a price increase on Lantus effective today: 16.1% vial and 9.9% pen. Based on our PC discussion on 5/19/2014, we agreed that the best strategy for Levemir® is to observe the market and maintain list price parity to competitors. As such, we will be moving forward with a 16.1% increase on Levemir® vial and a 9.9% increase on Levemir FlexPen® and FlexTouch® effective tomorrow 5/31/2014." Novo Nordisk then followed through, matching Sanofi's list price increases precisely, to the tenth of a percent. And by doing so netted the company approximately \$125 million in additional revenue.¹³³

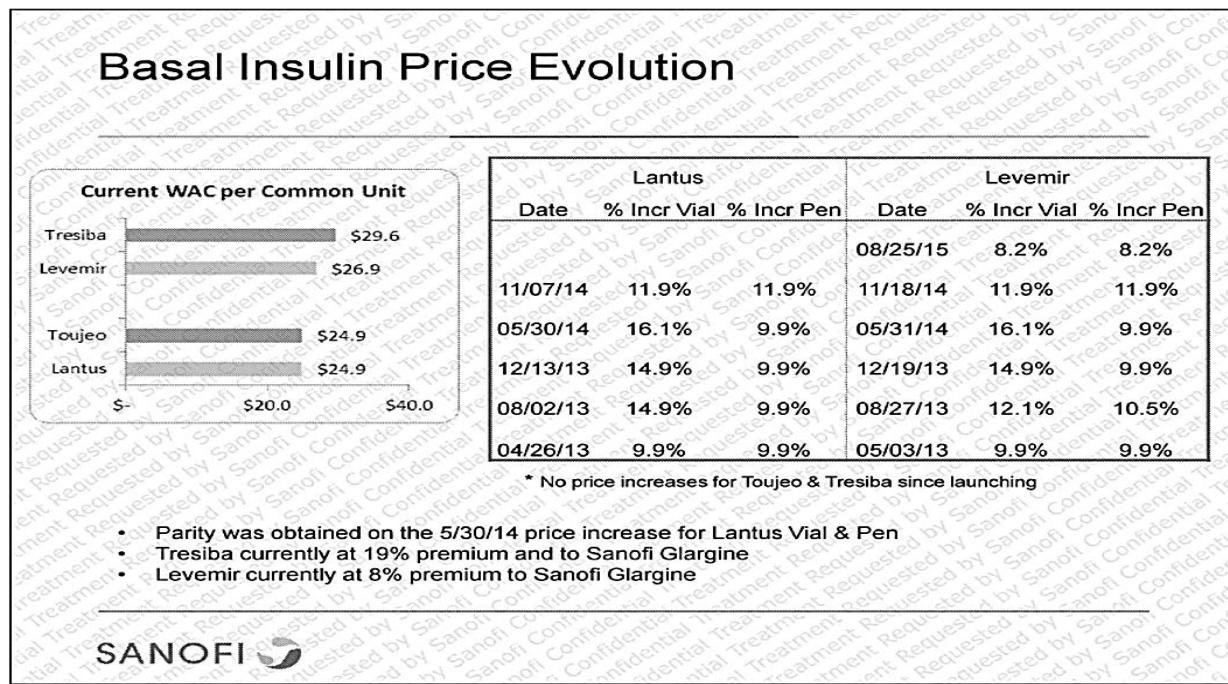
303. Novo Nordisk continued to track Sanofi's pricing actions and responded with incredible speed. In November 2014, Sanofi again raised the list price of Lantus vials and pens 11.9%; within hours, Novo Nordisk's pricing committee sought (and ultimately received) approval to raise, by 11.9%, the price of

¹³³ Staff of S. Comm. on Fin, 116th Cong., Rep. on Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug 54 (Comm. Print 2021), <https://www.finance.senate.gov/imo/media/doc/Insulin%20Committee%20Print.pdf..>

Levemir.¹³⁴ Rich DeNunzio of Novo Nordisk estimated the increase would generate approximately an additional \$25 million in revenue to the company in 2014 (despite the hike being taken at the end of the year).¹³⁵

304. An internal Sanofi chart also shows that, between April 2013 and November 2014, each time Sanofi raised the price of Lantus, Novo Nordisk followed suit for Levemir:

Figure 14: Sanofi price-tracking



305. Eli Lilly and Novo Nordisk also engaged in this lockstep pricing with respect to their Insulin Drugs. On May 30, 2014, a senior vice president at Eli Lilly sent a proposal to Enrique Conterno—then-President of Lilly Diabetes—for June

¹³⁴ *Id.* at 55.

¹³⁵ *Id.* at 56.

2014 price increases for Humalog and Humulin. The executive reported that Novo Nordisk had just executed a 9.9% price increase across its insulin portfolio. Mr. Conterno remarked, “While the list price increase is higher than we had planned, I believe it makes sense from a competitive perspective.” Eli Lilly took a 9.9% price increase shortly thereafter, on June 5, 2014.

306. Six months later, on November 19, 2014, Mr. Conterno reported to then-CEO John Lechleiter that Novo Nordisk had increased its price of NovoLog, the direct competitor to Eli Lilly’s Humalog, by 9.9%. Mr. Conterno wrote, “[a]s you are aware, we have assumed as part of our business plan a price increase of 9.9% for Humalog before the end of the year.” The following Monday, less than a week from Mr. Conterno’s email to the CEO, Eli Lilly increased prices of all Humalog and Humulin products by 9.9%.

307. Figure 15 demonstrates this behavior with respect to Humulin and Novolin. Figure 16 demonstrates this shadow pricing behavior with respect to the long-acting insulins while Figure 17 shows rising insulin prices specific to Lantus and Levemir. Figure 18 demonstrate this behavior with respect to rapid-acting insulins—Novolog, Fiasp, Humalog, and Apidra—while Figure 19 shows rising insulin prices specific to Humalog and Novolog.

Figure 15: Rising list prices of human insulins

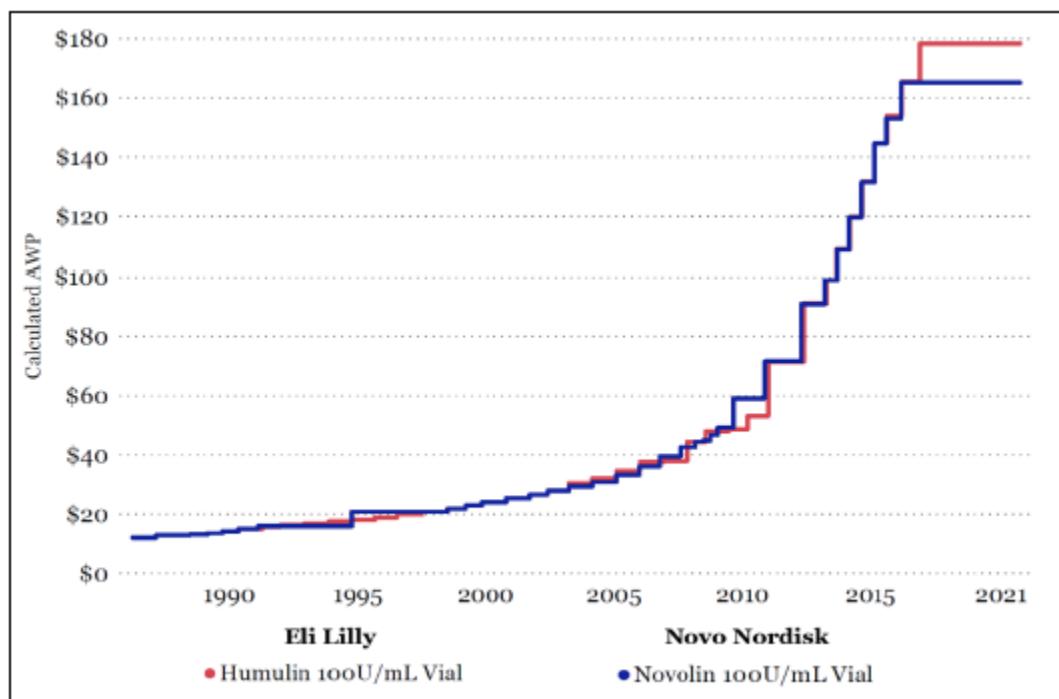


Figure 16: Rising list prices of long-acting insulins from 2006-2021

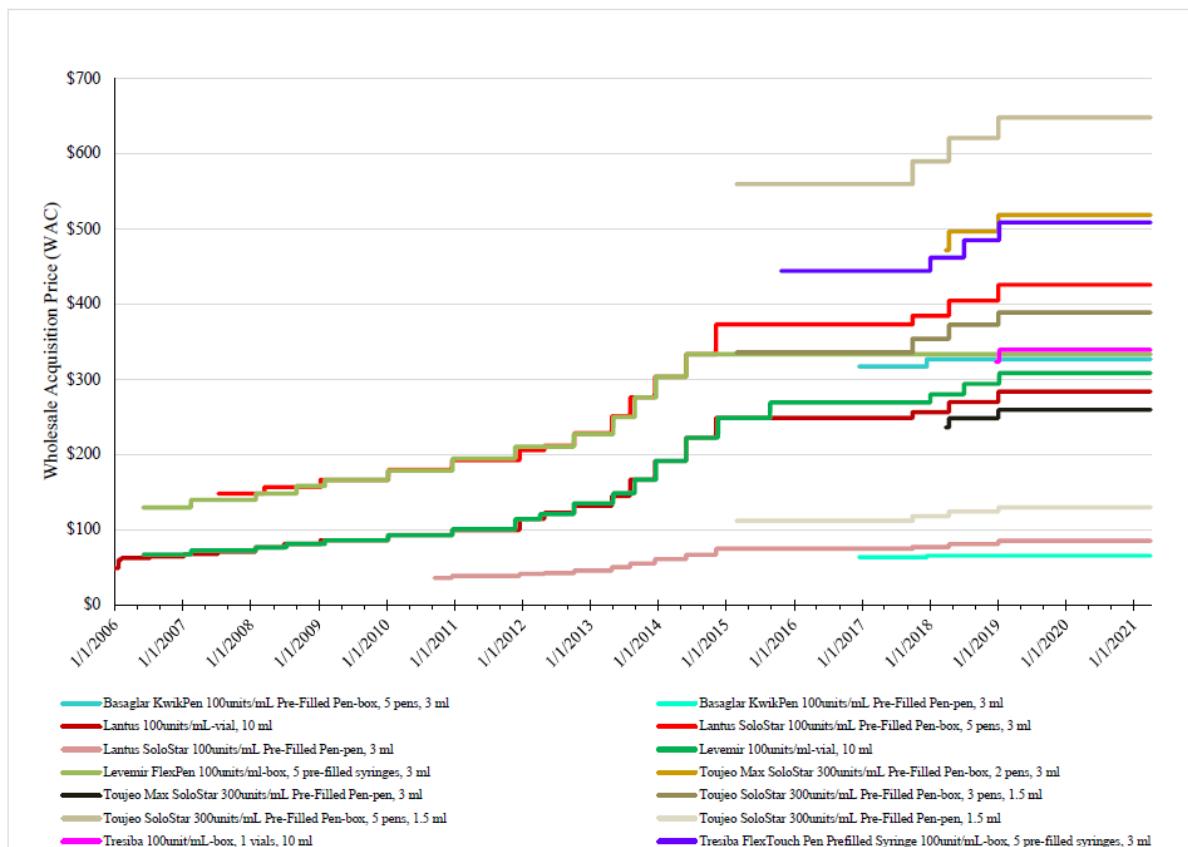


Figure 17: Rising Lantus and Levemir list prices from 2001-2015

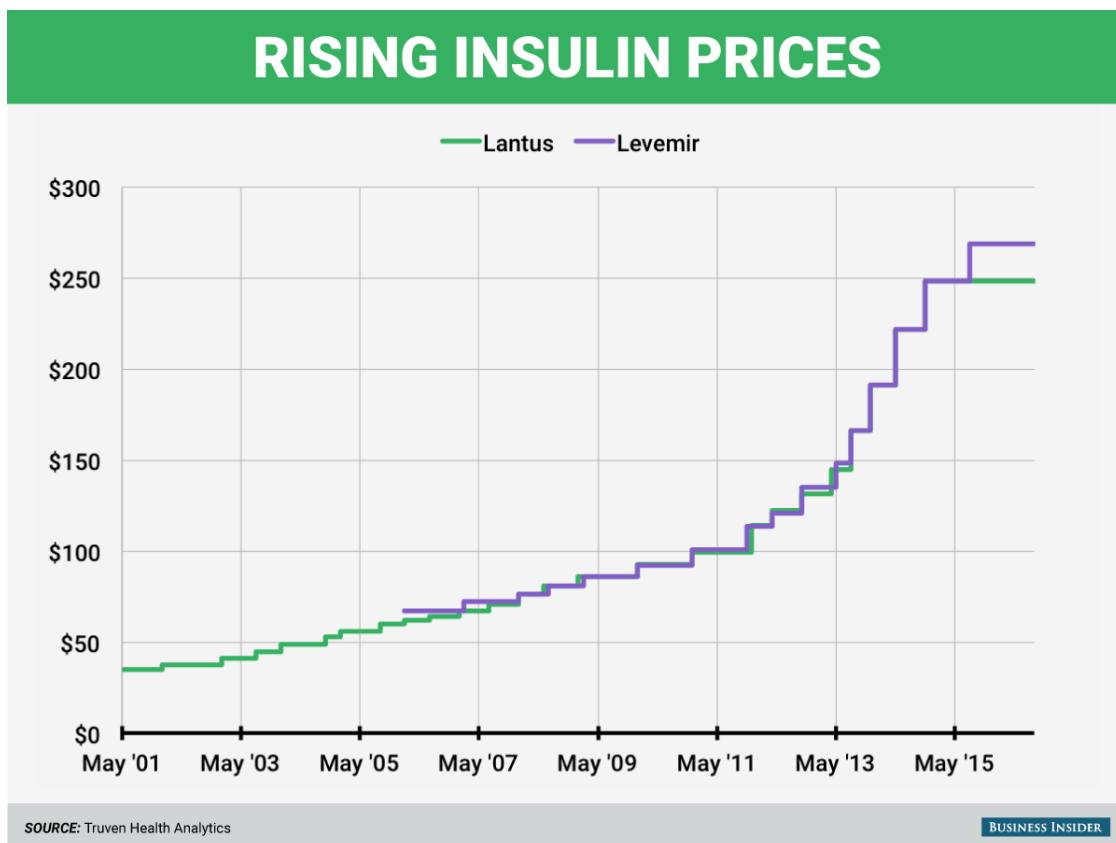


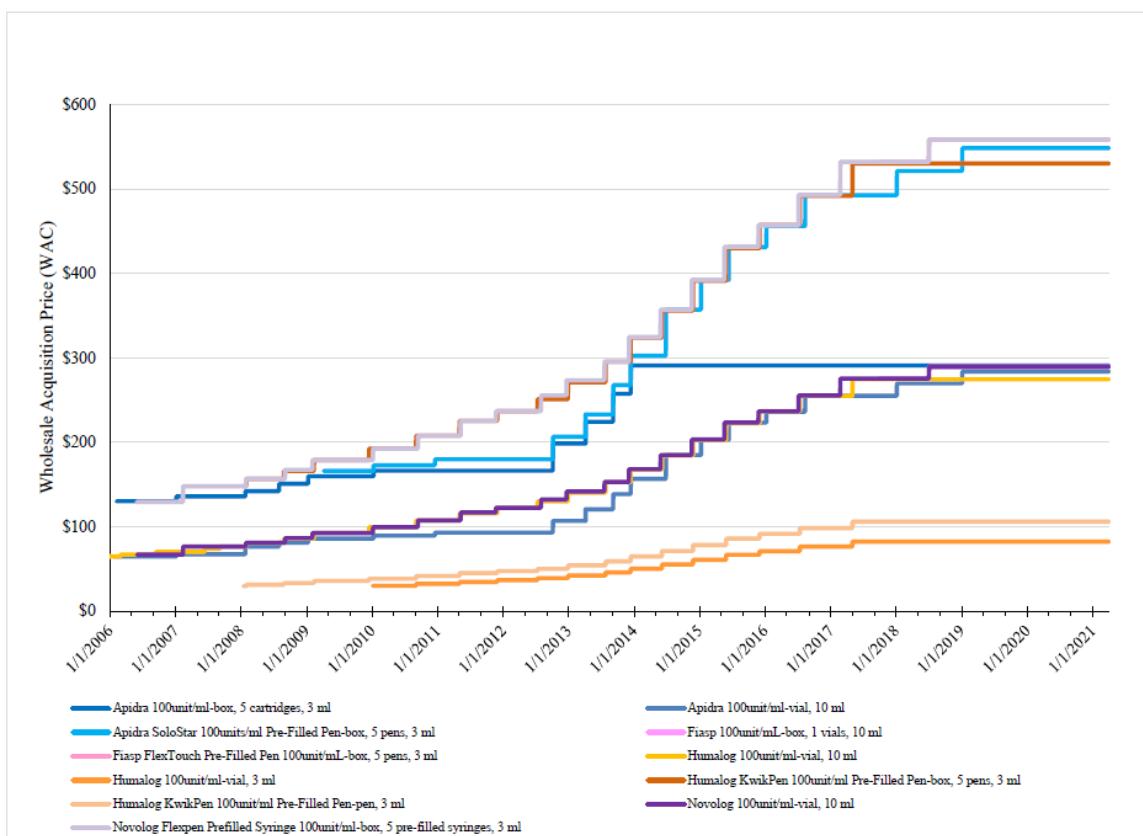
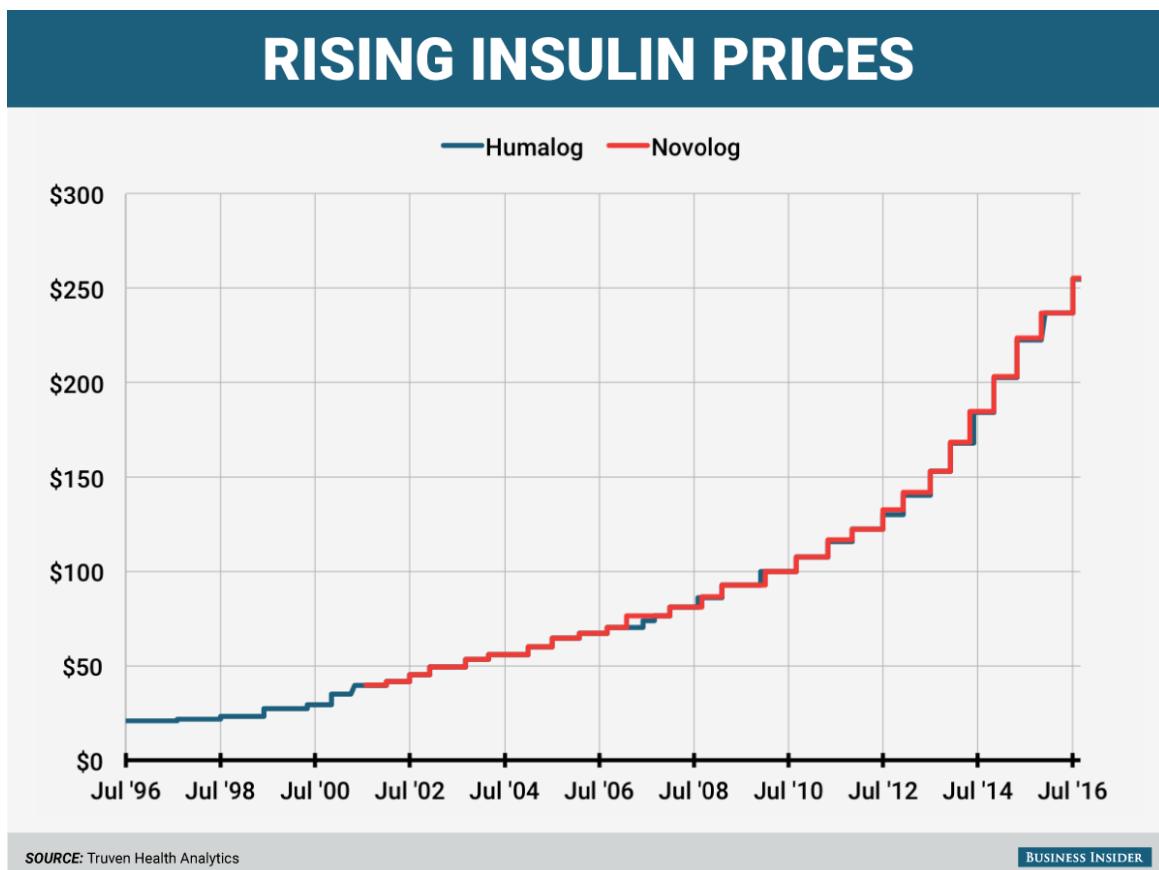
Figure 18: Rising list prices of rapid-acting insulin from 2006-2021

Figure 19: Rising Humalog and Novolog list prices from 1996-2016



E. Eli Lilly, Novo Nordisk, and Sanofi Have Sold Increased Spreads to PBMs in Exchange for (or as a Kickback for) Preferred Formulary Status

308. In the past, Novo Nordisk maintained that its price increases reflected the “clinical benefit” of its drugs.¹³⁶ But Levemir and Novolog are the exact same drugs they were more than 10 years ago—the clinical benefits of these medications have not changed. Where clinical benefit has not changed, it cannot be used to justify a 169% price increase. Therefore, another factor motivates these list price increases.

¹³⁶ Allison Tsai, *The Rising Cost of Insulin*, Diabetes Forecast (Mar. 2016), <http://www.diabetesforecast.org/2016/mar-apr/rising-costs-insulin.html>.

309. Research and development costs do not account for these list price increases, as such have been a fraction of revenues. For example, during the period of 2014-2018, Sanofi reported net sales of \$37 billion for its insulin products with R&D costs of \$902 million. In the same time period, Eli Lilly spent \$395 million on R&D with \$1.4 billion in sales and marketing expenses on revenues of \$22.4 billion.

310. The real reason Eli Lilly, Novo Nordisk, and Sanofi increased their list prices for the Insulin Drugs is because these firms choose to compete based on hidden rebates, fees, and other payments to PBM Defendants, rather than transparent prices for all. PBM Defendants control the formularies that determine whether people living with diabetes will purchase Eli Lilly, Novo Nordisk, or Sanofi's Insulin Drugs. Manufacturer Defendants have realized that they can manipulate the PBM Defendants' formulary choices by artificially inflating their list prices, rather than lowering net prices.

311. Even when versions of the same drug with a lower list price were available, the PBM Defendants methodically disfavored the low list price products on their formularies and preferred the high list price version, with which came high rebates and fees. As a Novo Vice President observed, "low wac/low rebate [insulins] don't stand a chance in this system," despite the fact that many patients may have been able to better afford the low WAC [list price] insulins as opposed to the high WAC [list price] insulins.

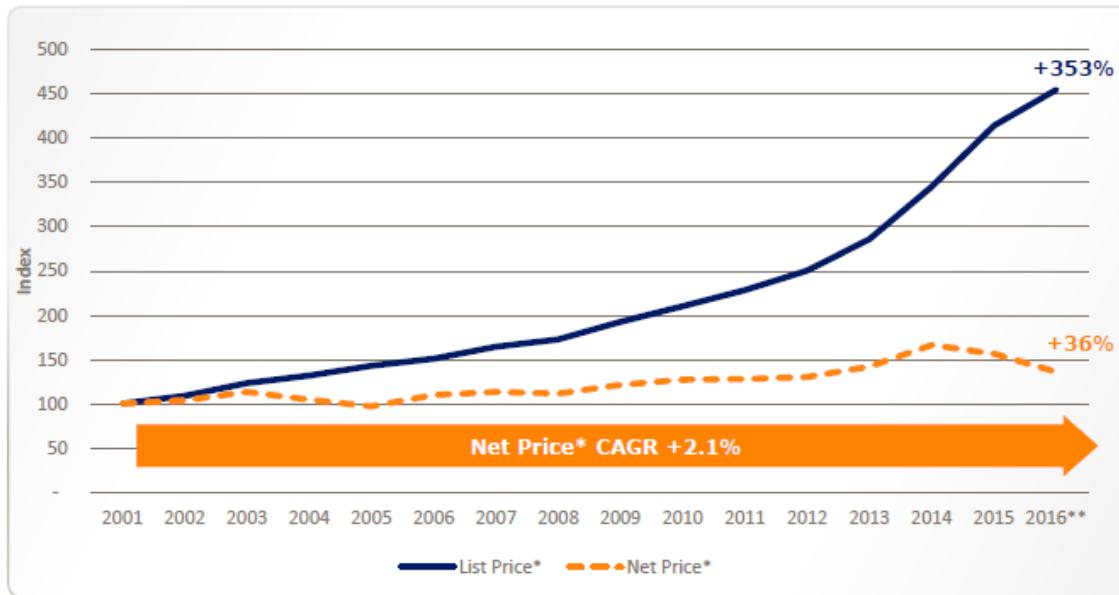
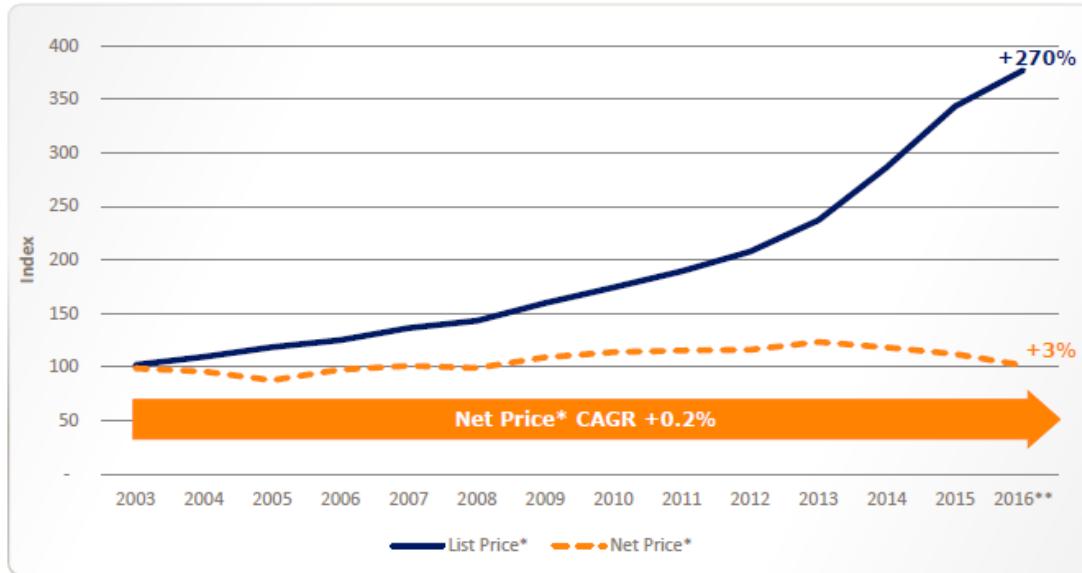
312. Under pressure to explain its rising list prices, Novo Nordisk admitted to this behavior in a press release. On November 30, 2016, Novo Nordisk stated:

We hear from more and more people living with diabetes about the challenges they face affording healthcare, including the medicines we make . . . News reports on drug prices have left the public with an impression that companies like ours realize all the profits from the “list price” increases we’ve made over the last decade. In other words, a list price increase by **XX percent leads to an automatic XX percent profit** for the drug maker. We believe that is misleading and here’s why: As the manufacturer, we do set the “list price” and have full accountability for those increases. However, after we set the list price, we negotiate with the companies that actually pay for the medicines, which we call payers. This is necessary in order for our medicines to stay on their preferred drug list or formulary. The price or profit we receive after rebates, fees and other price concessions we provide to the payer is the “net price.” The net price more closely reflects our actual profits.¹³⁷

313. Explaining the company’s list price increases, Novo Nordisk directly admitted that it “set[s] list price” with an eye to achieving “preferred” formulary status.

314. For over a decade, Novo Nordisk has steeply raised the list prices of Levemir and Novolog while keeping the net prices of these medicines constant. Figures 20 and 21 (included in Novo Nordisk’s press release) illustrate this conduct.

¹³⁷ Novo Nordisk Press Release (Nov. 30, 2016), <http://press.novonordisk-us.com/leadership-perspectives?item=1>.

Figure 20: Net versus List Prices of Novolog Vials¹³⁸**NovoLog® Vial****Figure 21: Net versus List Prices of Novolog FlexPens¹³⁹****NovoLog® FlexPen**¹³⁸ *Id.*¹³⁹ *Id.* The FlexPen is a type of insulin injection. Patients who use this pen stick themselves with a pen-like insulin distributor instead of injecting insulin through a pump or syringe.

315. Eli Lilly, too, has admitted that it raises list prices as a *quid pro quo* for formulary positions: “The reason drugmakers sharply raise list prices without a corresponding increase in net price is that PBMs demand higher rebates in exchange for including the drug on their preferred-drug lists.”¹⁴⁰

316. Sanofi has also conceded its participation in this pricing and kickback scheme: “[S]ince 2014, we have increased the level of rebates granted for Lantus® in order to maintain favorable formulary positions with key payers in the US.”¹⁴¹

317. Sanofi’s manipulation of its spreads is visible in Figure 22.

Figure 22: Net versus List Price of Lantus



Sources: Truven Health Analytics (list prices) and Bernstein (net price estimates)

THE WALL STREET JOURNAL.

¹⁴⁰ Denise Roland & Peter Loftus, *Middlemen Fuel Insulin Price Rise at B1*, Wall St. J. (Oct. 10, 2016).

¹⁴¹ Sanofi, Annual Report (Form 20-F) (Dec. 31, 2016).

318. Moreover, the Manufacturer Defendants and the PBM Defendants regularly communicate regarding setting the prices of insulins. For example, a June 23, 2018 email from Eli Lilly's Mr. Conterno, memorialized a conversation with the CEO of OptumRx, who "re-stated that [OptumRx] would be fully supportive of Lilly pursuing a lower list price option," but indicated that OptumRx would encounter challenges, namely, "the difficulty of persuading many of their customers to update contracts without offering a lower net cost to them."

319. Then, in response, an Eli Lilly executive noted, "we wouldn't be able to lower our list price without impacting our net price," and suggested waiting until early 2020 to reduce prices. Two weeks before this email, Eli Lilly executives had raised the possibility that PBMs would object to a list price reset because it would, among other things, (a) result in a reduction in administrative fees for PBMs, (b) reduce rebates, which would impact PBMs' ability to satisfy rebate guarantees with some clients, and (c) impair their clients' ability to lower premiums for patients, thereby impacting their market competitiveness. An excerpt of this email is shown below:

Figure 23: Eli Lilly internal email re potential price reductions

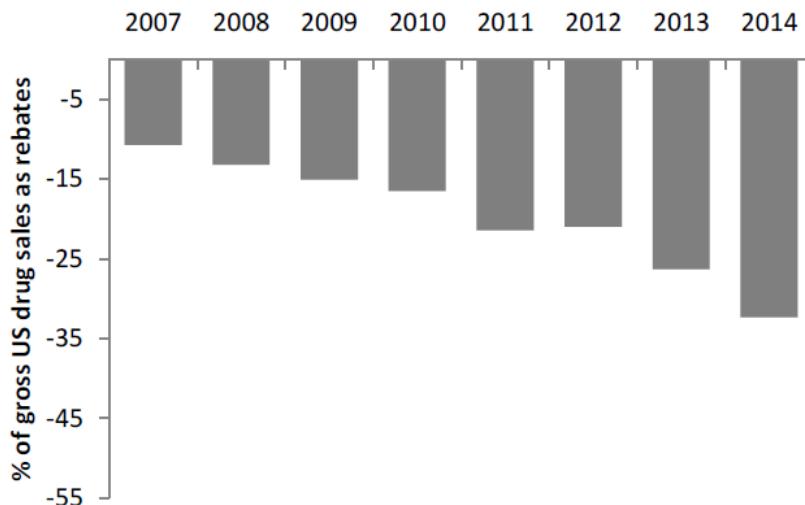


320. Eli Lilly's, Novo Nordisk's, and Sanofi's spread-increasing behavior is also visible from data on these companies' "rebates" to PBMs and insurers.

321. The two figures below illustrate Eli Lilly's "rebates" from 2007 to 2014. Figures 24 and 25 show the amount Eli Lilly has increased its rebates (spreads) from 2007 to 2014.

Figure 24: Eli Lilly's reported "rebates" as a percentage of U.S. gross sales from 2007-2014

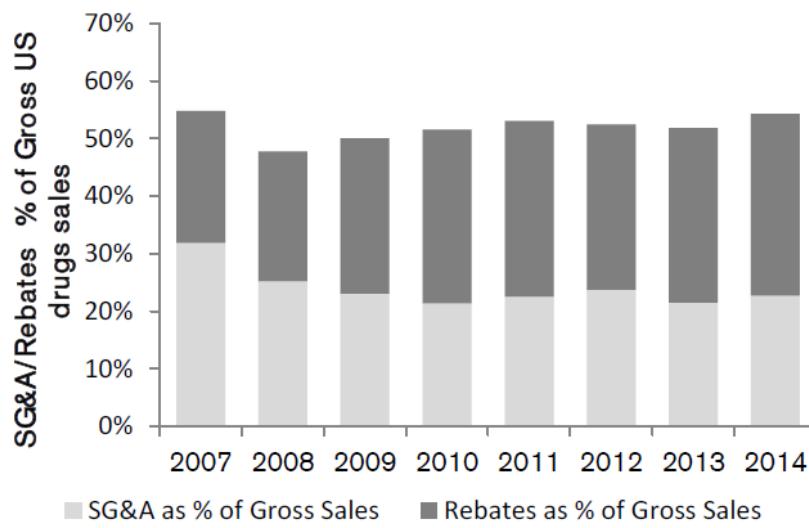
Figure 45: Reported rebates as % of US Gross sales



Source: Company data, Credit Suisse estimates

Figure 25: Eli Lilly's selling, general, and administrative costs and rebates as a percentage of gross U.S. sales from 2007-2014

Figure 46: SG&A and Rebates as % of US Gross



Source: Company data, Credit Suisse estimates

322. Novo Nordisk has also greatly increased its spreads. Figures 26 and 27 show the amount Novo Nordisk has increased its rebates (spreads) from 2007 to 2014.

Figure 26: Novo Nordisk's reported "rebates" as a percentage of U.S. gross sales from 2007-2014

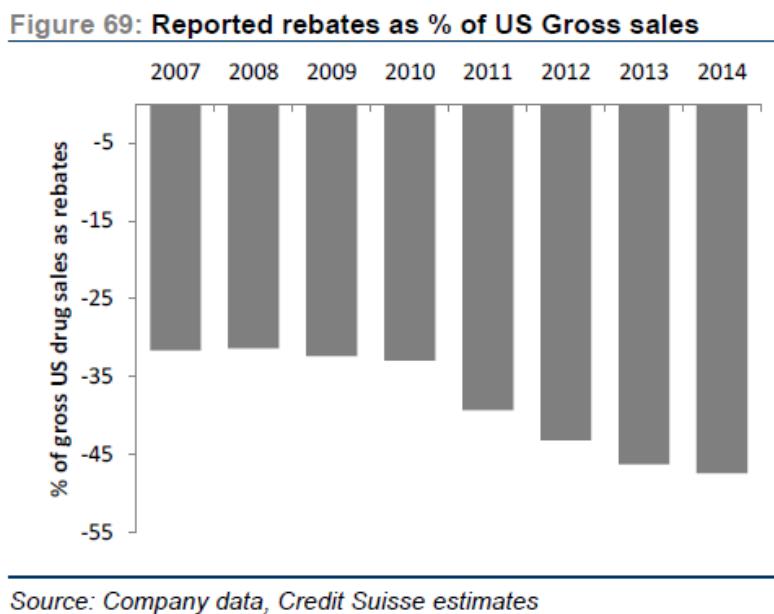
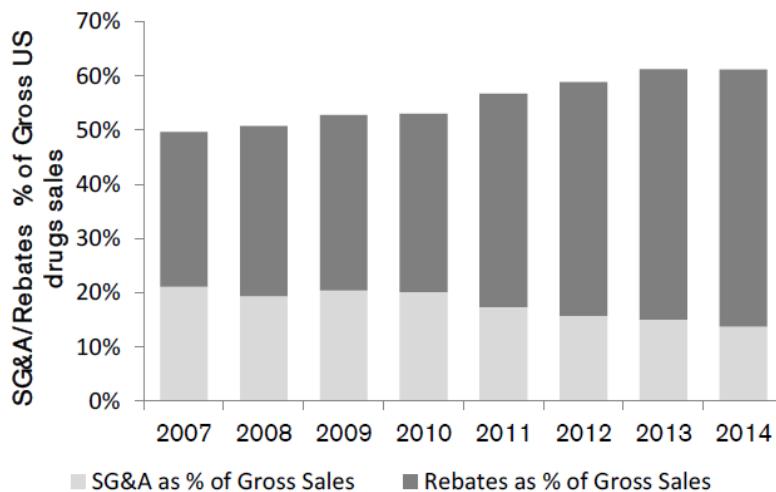


Figure 27: Novo Nordisk's selling, general, and administrative costs and rebates as a percentage of gross U.S. sales from 2007-2014

Figure 70: SG&A and Rebates as % of US Gross

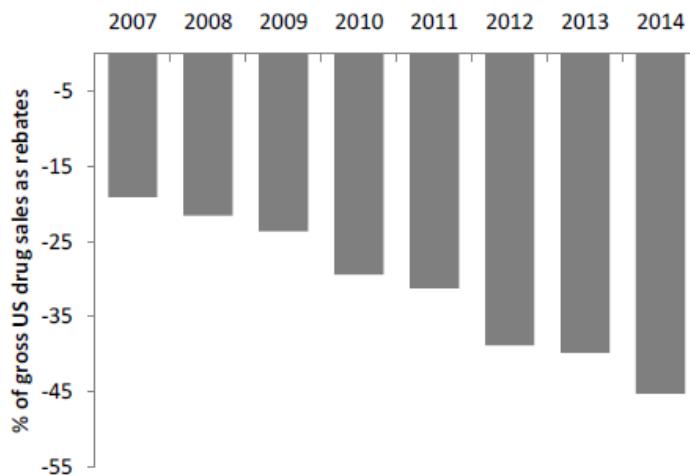


Source: Company data, Credit Suisse estimates

323. Finally, Sanofi has greatly increased its spreads. Figures 28 and 29 show the amount Sanofi has increased its rebates (spreads) from 2007 to 2014.

Figure 28: Sanofi's reported “rebates” as a percentage of U.S. gross sales from 2007-2014

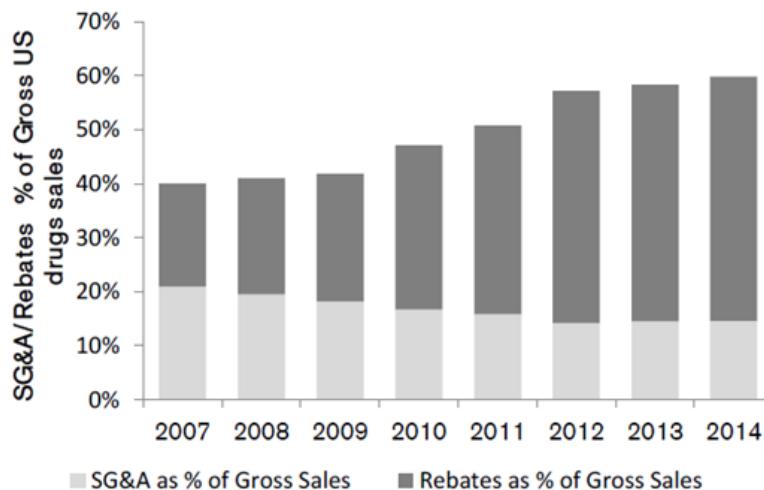
Figure 81: Reported rebates as % of US Gross sales



Source: Company data, Credit Suisse estimates

Figure 29: Sanofi's selling, general, and administrative costs and rebates as a percentage of gross U.S. sales from 2007-2014

Figure 82: SG&A and Rebates as % of US Gross



Source: Company data, Credit Suisse estimates

324. The arbitrary and deceptive nature of Manufacturer Defendants' list prices are underscored by how they price drugs to achieve "parity" when a new product launches. One would expect when a new insulin hits the market, older insulins would become more affordable as some patients flock to the newer and ostensibly more desirable medicines. But the opposite happens. Instead, the Manufacturer Defendants *inflate* the price of their older insulin products so that they can launch the newer insulins at higher prices and still ensure that consumers switch to those newer, more expensive insulins. If the drug manufacturers did not raise the list prices of their older medications, consumers would just stay on those medications rather than making the switch to the new ones. For example, in 2014, Sanofi aggressively began raising the list price of Lantus to achieve "a single price

point for Lantus . . . believing that it would remove cost as a barrier for switching patients to Toujeo to become the preferred basal insulin.”¹⁴²

325. Sanofi and Novo Nordisk have stretched the spreads on their Insulin Drugs to the point where they have become the second and third largest rebators in the entire pharmaceutical industry.

326. Although the Manufacturer Defendants claim they “need” to inflate their list prices to obtain formulary status, this explanation omits a crucial detail. Drug companies could compete for formulary status in a manner that would help Other Direct Purchasers, TPPs, and consumers: *they could significantly lower list (and net) prices.* Yet, the Manufacturer Defendants refuse to significantly lower their net prices, and the PBM Defendants continue to accept the Manufacturer Defendants’ list-price-raising behavior so long as net prices stay constant (and thereby PBM’s fees remain high).

327. The PBM Defendants collect more money from higher list price products, not because the products are administered more efficiently, but because the rebates and fees are based on a percentage of the list price. And the PBM Defendants provide no additional service to justify the higher rebates and fees for higher list price products.

¹⁴² Staff of S. Comm. on Fin, 116th Cong., Rep. on Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug 51(Comm. Print 2021), <https://www.finance.senate.gov/imo/media/doc/Insulin%20Committee%20Print.pdf..>

328. Indeed, upon facing pressure from lawmakers to lower their list prices in recent years, the Manufacturer Defendants analyzed the pros-and-cons of doing so. But Novo Nordisk, for example, lamented not being able to compete without massive rebates and feared retaliation in the supply chain from PBMs and others who benefit from the practice of inflating list price and then buying formulary access with rebates.¹⁴³

F. Manufacturer Defendants Have Engaged in “Bundling” Insulin Drugs with GLP-1 Drugs in Furtherance of Their Scheme To Drive Up the Price of Insulin Drugs.

329. In more recent years, the Manufacturer Defendants have released multiple non-insulin drugs that assist diabetics with controlling insulin levels known as GLP-1 drugs. GLP-1 drugs mimic the GLP-1 hormone produced in the body.¹⁴⁴

330. First, in 2010, Novo Nordisk began selling Victoza. Later, Eli Lilly released Trulicity and Sanofi released Soliqua. Novo Nordisk also later expanded the number of GLP-1 drugs it sells by obtaining approval for Xultophy¹⁴⁵ and Ozempic. Moreover, in 2022, Eli Lilly obtained approval for Mounjaro, another GLP-1 drug.

¹⁴³ Staff of S. Comm. on Fin, 116th Cong., Rep. on Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug 62 (Comm. Print 2021), <https://www.finance.senate.gov/imo/media/doc/Insulin%20Committee%20Print.pdf>.

¹⁴⁴ GLP-1 drugs include Ozempic, Soliqua, Trulicity, Victoza, Tanzeum, Mounjaro (Tirzepatide/GIP), Xultophy (insulin degludec/liraglutide), Rybelsus (semaglutide tablets), and Adlyxin (lixisenatide).

¹⁴⁵ Soliqua and Xultophy are combination long-acting insulin and GLP-1 drugs.

331. In a practice known as “bundling,” the Manufacturer Defendants negotiate rebates and other fees with the PBM Defendants by offering “bundles” of GLP-1 drugs with insulin. In this “bundling” practice, the Manufacturer Defendants package both insulin and GLP-1 drugs as a single class of diabetes medications.

332. The Manufacturer Defendants engage in this “bundling” practice in order to gain formulary access for multiple drugs in exchange for increased manufacturer payments to the PBMs.

333. As an example of this bundling practice used by the Manufacturer Defendants with insulin and GLP-1 drugs, Novo Nordisk “secured contract terms from CVS’s Part D business in 2013 that tied its ‘exclusive’ rebates for insulin to formulary access for a [GLP-1] drug called Victoza.”¹⁴⁶ Specifically, Novo Nordisk offered exclusive rebates for Novolin, Novolog, and Novolog Mix 70/30 that “were more than three times higher than the 18% rebate for plans that included two insulin products on their formulary.”¹⁴⁷ However, “[i]n order to qualify for the exclusive rebate, the plans would also need to list Victoza, a GLP-1 agonist, on their formulary, exclude all competing insulin products, and ensure ‘existing patients using a [c]ompeting [p]roduct may not be grandfathered.’”¹⁴⁸

¹⁴⁶ *Id.* at 71.

¹⁴⁷ *Id.*

¹⁴⁸ *Id.*

334. Upon information and belief, the Manufacturer Defendants similarly negotiate the prices of other insulin product and their GLP-1 products through this type of bundling.

G. The Artificial Inflation of List Prices Harms Plaintiffs and Class Members

335. The inflated list prices have harmed Class members. As the Manufacturer Defendants' list prices soared further and further away from their net prices, these list prices became so misrepresentative, so untethered from their true average prices, as to be unlawful.

336. The Manufacturer Defendants concealed their Insulin Drugs' net prices to ensure that the PBM Defendants could and would benefit from the spreads between the net and list prices. Put another way, the Manufacturer Defendants' publication of their list prices, while concealing their net prices, is the basis for the *quid pro quo* with the PBM Defendants. Defendants' pricing and kickback scheme enabled the Manufacturer Defendants to offer something of value to the PBM Defendants (large spreads on which to make profits) in exchange for preferred formulary status. If the Manufacturer Defendants did not have these spreads to offer, they would have been forced to compete for preferred formulary status through lower list prices. Put simply, the Manufacturer Defendants would have competed for the PBM Defendants' business the way competitors do in healthy markets: by lowering the prices. Such competition would have benefited Plaintiffs and Class

members, who make payments based on WAC. But instead of competing on lower prices, each of the Manufacturer Defendants competed on a larger spread.

337. To do so, the Manufacturer Defendants closely guarded their pricing structures and sales figures for the Insulin Drugs. Each of the Manufacturer Defendants kept secret the net prices it offered to the PBM Defendants and the amount of the rebates or unearned “fees” it pays to them.

338. Each Defendant also concealed its fraudulent conduct by signing confidentiality agreements with those in the supply chain that knew the net prices.

339. The PBM Defendants were complicit in artificially inflating the list price of the Insulin Drugs and concealing the amount of rebates and unearned “fees” paid for preferential formulary treatment of higher priced drugs.

340. The PBM Defendants ensured that the Manufacturer Defendants’ artificially inflated list prices harmed diabetics and TPPs by selecting the Insulin Drugs with higher spreads (and higher list prices) for preferred formulary placement, and by forcing TPPs to pay based on the inflated prices.

341. To further its purposes, the PBM Defendants have made misrepresentations about the Insulin Drugs and the prices thereof, including:

- a. In 2016, Glen Stettin, Senior Vice President and Chief Innovation Officer at Express Scripts, said in an interview with a national publication that “[d]iabetes is wreaking havoc on patients, and it is also a runaway driver of costs for payors . . . [Express Scripts] helps our clients and diabetes patients prevail over cost and care challenges

created by this terrible disease.”¹⁴⁹ Mr. Stettin also claimed that Express Scripts “broaden[s] insulin options for patients and bend[s] down the cost curve of what is currently the costliest class of traditional prescription drugs.”¹⁵⁰

- b. In a public statement issued in November 2010, CVS Caremark represented that it was focused on diabetes to “help us add value for our PBM clients and improve the health of plan members . . . a PBM client with 50,000 employees whose population has an average prevalence of diabetes could save approximately \$3.3 million a year in medical expenditures.”¹⁵¹
- c. In 2010, Andrew Sussman, Chief Medical Officer of CVS Caremark, stated on national television that “CVS is working to develop programs to hold down [diabetes] costs.”¹⁵²
- d. In a public statement issued in November 2012, CVS Caremark represented that formulary decisions related to insulin products “is one way the company helps manage costs for clients.”¹⁵³
- e. CVS Caremark’s Chief Policy and External Affairs Officer claimed in the April 2019 hearings that CVS Caremark “has taken a number of steps to address the impact of insulin price increases. We negotiate the best possible discounts off the manufacturers’ price on behalf of employers, unions, government programs, and beneficiaries that we serve.”¹⁵⁴

¹⁴⁹ Angela Mueller, *Express Scripts Launches Program to Control Diabetes Costs*, St. Louis Bus. J. (Aug. 31, 2016) <https://www.bizjournals.com/stlouis/news/2016/08/31/express-scripts-launches-program-to-control.html>.

¹⁵⁰ *Id.*

¹⁵¹ CVS Caremark 2010 Annual Report, https://s2.q4cdn.com/447711729/files/doc_financials/annual/cvs-ar-2010.pdf.

¹⁵² *Diabetes Epidemic Growing*, CBS News, (June 22, 2010), <https://www.cbsnews.com/news/diabetes-epidemic-growing/>.

¹⁵³ Jon Kamp & Peter Loftus, *CVS’ PBM Business Names Drugs It Plans to Block Next Year*, Wall St. J. (Nov. 8, 2012), <http://online.wsj.com/article/SB10001424127887324439804578107040729812454.html>.

¹⁵⁴ Priced Out of a Lifesaving Drug, ¶¶ 714-18.

f. Dr. Sumit Dutta, SVP and Chief Medical Officer of OptumRx, testified before the U.S. Congress in the April 2019 hearing that for “insulin products . . . we negotiate with brand manufacturers to obtain significant discounts off list prices on behalf of our customers.”¹⁵⁵

342. The PBM Defendants have further mislead the Plaintiffs and the public concerning their transparency on pricing negotiations. For example:

- a. In 2011, OptumRx’s President stated: “We want our clients to fully understand our pricing structure . . . [e]very day we strive to show our commitment to our clients, and one element of that commitment is to be open and honest about our pricing structure.”¹⁵⁶
- b. In a 2017 CBS News interview, Express Scripts’ CEO represented, among other things, that Express Scripts was “absolutely transparent” about the rebates and other payments they receive from manufacturers and that payors “know exactly how the dollars flow” with respect to these manufacturer payments.¹⁵⁷
- c. When testifying before the Senate Finance Committee, CVS Executive Vice President Derica Rice stated, “[A]s it pertains to transparency overall, we at CVS Caremark are very supportive. We provide full visibility to our clients of all our contracts and the discounts that we negotiate on their behalf . . . And transparency—today we report and fully disclose not only to our clients, but to CMS [Medicare].”¹⁵⁸
- d. At the same hearing, Steve Miller of Cigna (Express Scripts) testified: “we are really a strong proponent for transparency for those who pay for

¹⁵⁵ *Id.* at ¶¶ 904-06.

¹⁵⁶ *Prescription Solutions by OptumRx Receives 4th Consecutive TIPPS Certification for Pharmacy Benefits Transparency Standards*, UnitedHealth Group (Sept. 13, 2011), <https://www.businesswire.com/news/home/20110913006224/en/Prescription-Solutions-OptumRx-Receives-4th-Consecutive-TIPPSSM>.

¹⁵⁷ CBS News, *Express Scripts CEO Tim Wentworth Defends Role of PBMs in Drug Prices* (Feb. 7, 2017), <https://www.cbsnews.com/news/express-scripts-tim-wentworth-pbm-rising-drug-prices-mylan-epipen-heather-bresh/>.

¹⁵⁸ Drug Pricing in America: A Prescription for Change, Part III, Before the S. Fin. Comm. (Apr. 9, 2019), at 28, 32, <https://www.finance.senate.gov/imo/media/doc/435631.pdf>.

health care. So the patient should know exactly what they are going to pay. Our plan sponsors need to know exactly what is in their contract.”¹⁵⁹

- e. John Prince of OptumRx likewise stated: “Senator, if our discounts were publicly available, it would hurt our ability to negotiate effectively. Our discounts are transparent to our clients.”¹⁶⁰

343. However, PBM Defendants have never revealed the full amount of any drug-specific payments received from Manufacturer Defendants.

344. PBM Defendants do not disclose the terms of the agreements they make with Manufacturers Defendants. Further, although PBMs negotiate drug-specific rebates with drug manufacturers,¹⁶¹ PBM Defendants’ rebate payments to TPP clients and summaries of such payments are in the aggregate, rather than on a drug-by-drug basis. Thus, it is impossible for TPPs to discern drug-specific rebates. This allowed PBM Defendants to hide the large payments that they receive for the Insulin Drugs.

345. In sum, each Defendant concealed that: (i) the list prices for Insulin Drugs were fraudulently-inflated, (ii) it was manipulating the list prices of its Insulin Drugs, (iii) the list prices bore no relationship to the prices paid for, or the pricing structure of, the Insulin Drugs, and (iv) the net prices to the PBM Defendants were either held constant or else decreasing.

¹⁵⁹ *Id.* at 32.

¹⁶⁰ *Id.*

¹⁶¹ *Id.* at 40.

346. The Manufacturer Defendants' publication of their list prices, combined with their concealment of the rebates and net prices, deceived Plaintiffs and Class members into believing that the Insulin Drugs' list prices were reasonably related to the drugs' net prices.

347. Plaintiffs and Class members relied on Defendants' representations regarding the list prices for Insulin Drugs and paid for the Insulin Drugs based on these inflated list prices to their detriment. Plaintiffs and Class members continue to pay for the Insulin Drugs based on their list prices. Such payments are fraudulent given the value of these drugs as evidence by their true, net prices.

348. As a result of Defendants' deceptive conduct, Plaintiffs and Class members overpaid for their Insulin Drugs when they paid for these medications based on their list prices. No other entity in the drug supply chain sets these list prices and no other entity in the supply chain has the ability to change these list prices

VI. INTERSTATE TRADE AND COMMERCE

349. As described herein, during the Class Period, Defendants, directly or through one or more of their affiliates, sold the Insulin Drugs throughout the United States in a continuous and uninterrupted flow of interstate commerce, including through and into this District.

350. The business activities of Defendants that are the subject of this action were within the flow of, and substantially affected, interstate trade and commerce.

351. Defendants' and their co-conspirators' conduct, including the marketing and sale of the Insulin Drugs, has had, and was intended to have, a direct, substantial, and reasonably foreseeable anticompetitive effect upon interstate commerce within the United States.

352. Defendants' conduct as alleged in this Complaint has directly and substantially affected interstate commerce as Defendants deprived Plaintiffs and Class members of the benefits of free and open competition in the purchase of the Insulin Drugs within the United States.

VII. ANTITRUST AND RICO INJURY

353. As described herein, during the Class Period, Plaintiffs and Class members directly purchased the Insulin Drugs from the Defendants. As a result of Defendants' unlawful scheme, Plaintiffs and Class members paid more for the Insulin Drugs than they would have. This is a cognizable injury and constitutes compensable harm under the federal antitrust laws and the RICO statute.

354. As a result of Defendants' unlawful conduct, Plaintiffs and Class members have sustained, and continue to sustain, significant losses in the form of artificially inflated prices paid for the Insulin Drugs and the retention by the PBM Defendants of the unearned rebates and fees that are not paid for the delivery of any

service. The full amount of such damages will be calculated after discovery and upon proof at trial.

355. Further, the PBMs were and are the agents and/or fiduciaries of the TPP Plaintiffs and TPP Class members in their role as intermediaries with the Manufacturer Defendants for the TPP Plaintiffs and TPP Class members, and breached duties owed to the TPP Plaintiffs and TPP Class members by taking bribes in the form of inflated payments from the Manufacturer Defendants in exchange for placing the Insulin Drugs on their formularies.

356. TPP Plaintiffs and TPP Class members were directly injured by the illicit scheme between the PBM Defendants and the Manufacturer Defendants both because they directly purchased Insulin Drugs with artificially inflated prices from the Defendants' mail order pharmacies and because the TPP Plaintiffs and TPP Class members hire the PBM Defendants to work on their behalf to obtain the best possible prices for prescription drugs and the illicit scheme undermined the agent and/or fiduciary relationship between the PBM Defendants and the TPP Plaintiffs and TPP members of the Class.

357. Other Direct Purchaser Plaintiffs were directly injured by the illicit scheme between the PBM Defendants and the Manufacturer Defendants because they directly purchased drugs from the Manufacturer Defendants and, thus, were substantially impacted by the artificially inflated prices of the Insulin Drugs. The

apportionment of damages here will be straightforward because the injury sustained is based on the inflated prices paid by Plaintiffs and Class members.

VIII. TOLLING OF THE STATUTE OF LIMITATIONS

A. Continuing Violations/Separate Accrual Doctrine

358. The conduct of Defendants central to Plaintiffs' and Class members' claims has not ceased; the pricing and kickback scheme remains in effect. And all of the relevant conduct of Defendants is part of a continuing unlawful practice. Accordingly, under the continuing violations/separate accrual doctrine, this action is timely because the last act evidencing the continuing practice falls within the applicable limitation periods.

B. Fraudulent Concealment Tolling

359. All applicable statutes of limitation have also been tolled by Defendants' knowing and active fraudulent concealment and denial of the facts alleged herein throughout the period relevant to this action.

C. Estoppel

360. Defendants were under a continuous duty to disclose to Plaintiffs and Class members the true character, quality, and nature of the list prices upon which their payments for insulin were based.

361. Based on the foregoing, Defendants are estopped from relying on any statutes of limitations in defense of this action.

D. Relation Back/*American Pipe* Tolling

362. All Plaintiffs and Class members assert claims herein arising out of the conduct, transactions, and occurrences set forth in the original complaints filed by FWK Holdings, LLC and Rochester Drug Cooperative, Inc., on March 31, 2020. *See FWK Holdings, LLC v. Novo Nordisk Inc. et. al.*, 20-cv-3480 at ECF No. 1 (“FWK Complaint”) and *Rochester Drug Cooperative, Inc. v. Eli Lilly and Co. et. al.*, 20-cv-3426 at ECF No. 1 (“Rochester Complaint”). Plaintiffs and Class members are also encompassed by the class definition in the FWK and/or Rochester Complaints and, accordingly, their claims were tolled pursuant to *American Pipe & Construction Company v. Utah*, 414 U.S. 538 (1974) and its progeny.

IX. CLASS ACTION ALLEGATIONS

363. Plaintiffs bring this action on behalf of themselves and all others similarly situated under Federal Rule of Civil Procedure 23(a), (b)(2) and (b)(3), as representatives of the following Class:

All entities in the United States of America and its territories that directly purchased Apidra, Basaglar, Fiasp, Humulin, Humalog, Lantus, Levemir, Novolin, Novolog, Tresiba, and/or Toujeo from one or more Defendants at any time from January 1, 2009 until [the date of the class certification order].

All entities in the United States of America and its territories that purchased directly from or contracted directly with one or more Defendants regarding the following drugs: Apidra, Basaglar, Fiasp, Humulin, Humalog, Lantus, Levemir, Novolin, Novolog, Tresiba, and/or Toujeo from January 1, 2009 until [the date of the class certification order]

In the alternative, Plaintiffs propose the following Class:

All entities in the United States of America and its territories that directly purchased Apidra, Basaglar, Fiasp, Humulin, Humalog, Lantus, Levemir, Novolin, Novolog, Tresiba, and/or Toujeo from any Manufacturer Defendant at any time from January 1, 2009 until [the date of the class certification order]; and

All entities in the United States of America and its territories that directly purchased Apidra, Basaglar, Fiasp, Humulin, Humalog, Lantus, Levemir, Novolin, Novolog, Tresiba, and/or Toujeo from any PBM Defendant at any time from January 1, 2009 until [the date of the class certification order].

364. Excluded from the Class are (i) governmental entities other than municipalities and/or local governments with self-funded prescription drug plans; (ii) fully insured health plans, i.e., plans for which the insurer bears 100% of the risk for the reimbursement obligations to members; (iii) pharmacy benefit managers; (iv) natural person consumers; and (v) employees of Defendants, including their officers or directors, and subsidiaries and affiliates. The Class also excludes entities bringing non-Class claims in the Self-Funded Payer Track and the State Attorney General Track, as described in Case Management Order #2. *See* ECF No. 34 (Case No. 2:23-md-03080 BRM-RLS).

365. The Class Period is tolled to the earliest date of the initiation of the pricing and kickback scheme described herein, wherein Manufacturer Defendants artificially inflated the list prices of the Insulin Drugs to offer PBM Defendants kickbacks and higher spreads in exchange for preferred formulary status.

366. Plaintiffs believe there are at least hundreds (and more likely thousands) of Class members that are geographically dispersed throughout the United States. As a result, joinder of all members of the Class is impracticable.

367. Class members are readily identifiable from information and records maintained by Defendants.

368. Plaintiffs' claims are typical of the claims of the Class members. Plaintiffs and all Class members were damaged by the same wrongful conduct by Defendants—i.e., as a result of Defendants' misconduct, these purchasers made insulin purchases at artificially inflated prices, and they will continue to do so in the future.

369. Plaintiffs will fairly and adequately protect and represent the interests of the Class. The interests of Plaintiffs are coincident with, and not antagonistic to, those of the other Class members.

370. Counsel that represents Plaintiffs are experienced in the prosecution of class action litigation and have particular experience in RICO and antitrust cases involving pharmaceutical products.

371. Questions of law and fact common to the Class members predominate over questions that may affect only individual Class members because Defendants have acted on grounds generally applicable to the entire Class. As a result, calculating aggregate damages for the Class as a whole is appropriate.

372. Questions of law and fact common to the Class include, but are not limited to:

- i. Whether Defendants controlled and inflated the list price (WAC) of the Insulin Drugs;
- ii. Whether the Manufacturer Defendants engaged in a pattern and practice of paying illegal kickbacks, disguised as “rebates,” to the PBM Defendants that created substantial spreads between the list and net prices;
- iii. Whether the large list-to-net price spreads were intended to induce the PBM Defendants to give the Manufacturer Defendants’ Insulin Drugs favorable placement on the PBM Defendants’ formularies;
- iv. Whether the Manufacturer Defendants used artificially inflated list prices as a starting point for negotiating these kickbacks or “rebates” for the Insulin Drugs;
- v. Whether each Defendant conspired for the purpose of carrying out this pricing and kickback scheme;
- vi. Whether Plaintiffs and Class members overpaid based on the artificial list prices for the Insulin Drugs;
- vii. Whether the Manufacturer Defendants copied their competitors’ price increases such that all Insulin Drugs were infected by the pricing and kickback scheme;
- viii. Whether Defendants engaged in mail and wire fraud in carrying out their unlawful pricing and kickback scheme;
- ix. Whether Defendants engaged in commercial bribery in violation of 18 U.S.C. § 1341.
- x. Whether Manufacturer Defendants paid kickbacks to the PBM Defendants that provide ERISA benefit plan services to employer sponsored health benefit plans with the intention of influencing the choice of Insulin Drugs to include in the benefit plan formularies that determine whether and to what extent a particular insulin is available to patients on favorable terms in violation of 18 U.S.C. § 1954;

- xi. Whether Defendants engaged in commercial bribery in violation of the Travel Act, 18 U.S.C. § 1952;
- xii. Whether Defendants were engaged in one or more “enterprises” within the meaning of the federal RICO statute;
- xiii. Whether Defendants operated such RICO enterprise(s) through a pattern of racketeering activity including mail and wire fraud in violation of state law and 18 U.S.C. §§ 1341, 1343, 1952, and 1954.
- xiv. Whether the alleged illegal conduct engaged in by Defendants comprised racketeering activity, in violation of federal RICO laws;
- xv. Whether, and to what extent, Defendants’ RICO violations caused injury to Plaintiffs and Class members in their business, trade, or property; and
- xvi. Whether Defendants are liable to Plaintiffs and Class members for damages flowing from their misconduct.
- xvii. Whether Defendants engaged in a kickback scheme and thereby committed commercial bribery;
- xviii. Whether such conduct is a violation of Section 2(c) of the Robinson Patman Act.

373. Plaintiffs and Class members have all suffered, and will continue to suffer, harm and damages as a result of Defendants’ unlawful and wrongful conduct. A class action is superior to other available methods for the fair and efficient adjudication of this controversy under Rule 23(b)(3). Such treatment will permit a large number of similarly-situated TPP and Other Direct Purchasers to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism,

including providing injured entities a method for obtaining redress on claims that could not practicably be pursued individually, substantially outweighs potential difficulties in management of this class action. Absent a class action, most Class members likely would find the cost of litigating their claims to be prohibitive and will have no effective remedy at law. The class treatment of common questions of law and fact is also superior to multiple individual actions or piecemeal litigation in that it conserves the resources of the courts and the litigants and promotes consistency and efficiency of adjudication. Additionally, Defendants have acted and failed to act on grounds generally applicable to Plaintiffs and the Class and require Court imposition of uniform relief to ensure compatible standards of conduct toward the Class, thereby making appropriate equitable relief to the Class as a whole within the meaning of Rule 23(b)(2).

374. Plaintiffs know of no special difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

375. The Manufacturer Defendants concealed the Insulin Drugs' net prices and prevented Plaintiffs and Class members from knowing what these prices were to ensure the Manufacturer Defendants would not have to meaningfully lower the net prices of their Insulin Drugs. And so that PBMs could and would benefit from the spreads between the net and list prices. Put another way, Manufacturer Defendants' publication of their list prices, while concealing their net prices, is the

basis for the *quid pro quo* with the PBM Defendants. Defendants' pricing scheme enabled the Manufacturer Defendants to offer the PBM Defendants large spreads on which to make profits in exchange for preferred formulary status. If the Manufacturer Defendants did not have these spreads to offer, they would have been forced to compete for preferred formulary status through lower list prices. Put simply, without the pricing schemes, the Manufacturer Defendants would have competed for PBM Defendants' business the way competitors do in healthy markets: by lowering the prices. Such competition would have benefited Plaintiffs and Class members, but instead of competing on lower prices, each Manufacturer Defendant competed on a larger spread.

376. To do so, Defendants closely guarded their pricing structures and sales figures for their Insulin Drugs. Each Manufacturer Defendant kept secret the net prices it offered to the PBM Defendants.

377. Each Defendant also concealed its fraudulent conduct by signing confidentiality agreements with those in the supply chain that knew the net prices.

378. In sum, each Defendant concealed that: (i) the list prices for Insulin Drugs were fraudulently inflated, (ii) it was manipulating the list prices of Insulin Drugs, (iii) the list prices bore no relationship to the prices paid for, or the pricing structure of, the Insulin Drugs, and (iv) the net prices to the PBM Defendants were either held constant or else decreasing.

379. Defendants' publication of the list prices for Insulin Drugs, combined with their concealment of their net prices, deceived Plaintiffs and Class members into believing that the Insulin Drugs' list prices were reasonably related to the drugs' net prices.

380. Plaintiffs and the Class relied on the representations regarding their list prices and paid for the Insulin Drugs based on these inflated list prices to their detriment. Plaintiffs and the Class continue to pay for the Insulin Drugs based on their list prices. Such payments are fraudulent given the value of these drugs as evidenced by their true, net prices.

381. As a result of Defendants' scheme, Plaintiffs and Class members overpaid when purchasing Insulin Drugs based on their list prices. No other entity in the drug supply chain sets these list prices and no other entity in the supply chain has the ability to change these list prices, on which Other Direct Purchaser and TPP payments for insulin are directly based.

X. CLAIMS FOR RELIEF

A. COUNT ONE VIOLATIONS OF RICO, 18 U.S.C. § 1962(c) (Against All Defendants on behalf of all Plaintiffs and the Class)

382. Plaintiffs incorporates by reference the allegations contained in the preceding paragraphs.

383. Plaintiffs, on behalf of themselves and all others similarly situated, assert this claim on behalf entities that directly purchased Insulin Drugs from any Defendant. TPP Plaintiffs, on behalf of themselves and all others similarly situated, assert this claim to recover for those TPP purchases made from PBM-run mail order pharmacies only. Because TPP Plaintiffs, and similarly situated TPPs, purchased Insulin Drugs directly from the PBM Defendants, via their mail order pharmacies, they made direct purchases from the RICO enterprises described below.

384. Other Direct Purchaser Plaintiffs assert this claim on behalf of themselves and other similarly situated purchasers that directly paid the Manufacturer Defendants for Insulin Drugs. Because Other Direct Purchaser Plaintiffs and similarly situated Class members purchased Insulin Drugs directly from the Manufacturer Defendants, they made direct purchases from the RICO enterprises described below.

385. Under 18 U.S.C. § 1961(4), a RICO “enterprise” may be an association-in-fact that, although it has no formal legal structure, has (i) a common purpose, (ii) relationships among those associated with the enterprise, and (iii) longevity sufficient to pursue the enterprise’s purpose.

1. Defendants are Culpable “Persons” Under RICO

386. Plaintiffs bring this count against Defendants, as identified below, on behalf of the Class and alleges violations of Section 1962(c) of RICO, 18 U.S.C. § 1962(c).

387. Plaintiffs, Class members, and each Defendant are all “persons,” as that term is defined in 18 U.S.C. § 1961(3).

2. The Manufacturer-PBM Insulin Pricing RICO Enterprises

388. For purposes of this claim, the RICO “enterprises” are associations-in-fact consisting of (a) *one* of the three largest PBMs—CVS Caremark, Express Scripts, or OptumRx—that administers purchases of the Manufacturer Defendants’ Insulin Drugs, including its directors, employees, and agents, and (b) *one* of the Manufacturer Defendants, including its directors, employees, and agents. These associations-in-fact enterprises are collectively referred to herein as the “Manufacturer-PBM Insulin Pricing Enterprises.”

389. Each of the Manufacturer-PBM Insulin Pricing Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common and/or shared purposes of selling, purchasing, and administering the Insulin Drugs to Plaintiffs and Class members and deriving secret profits from these activities (the pricing and kickback scheme). These profits are greater than either the Manufacturer Defendants or the

PBM Defendants could obtain absent their fraudulent concealment of the substantial kickbacks and bribes misleadingly labeled as “rebates” or “fees” from the Manufacturer Defendants to the PBM Defendants.

390. As to each Enterprise, (i) there is a common communication network by which the particular Manufacturer Defendant and PBM Defendant respectively share information on a regular basis, and (ii) the particular Manufacturer Defendant and PBM Defendant function as continuing but separate units. At all relevant times, each Enterprise was operated and conducted by the particular Manufacturer Defendant and PBM Defendant for criminal and fraudulent purposes, namely, carrying out the bribery and kickback scheme.

391. Each Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common and/or shared purposes of selling, promoting, and recommending for purchase, and administering prescriptions for the Insulin Drugs and deriving secret profits from these activities.

392. To accomplish this common purpose, Defendants systematically artificially inflated the list prices of the Insulin Drugs and Manufacturer Defendants systematically paid bribes and kickbacks—falsely labeled as rebates, administrative fees, and/or other payments or compensation—to PBM Defendants in exchange for exclusive and/or favorable placement of their Insulin Drugs on the formularies

maintained by the PBM Defendants on behalf of their respective clients. They did so willfully, and with knowledge that Class members make payments directly based on the inflated list prices.

393. It is this scheme that is fraudulent. Manufacturer Defendants' benchmark prices are no longer a reasonable approximation of the actual price of Insulin Drugs, and the Manufacturer-PBM Insulin Pricing Enterprises concealed the magnitude of the spreads between benchmark prices and net prices from Plaintiffs and the Class. The Manufacturer-PBM Insulin Pricing Enterprises also concealed from the public the purpose of these spreads: the spreads ultimately result in higher profits for the Manufacturer Defendants, through ensuring formulary access without requiring significant price reductions; and they result in higher profits for the PBM Defendants, whose earnings increase as the spread between list and net prices grows.

394. Each Manufacturer-PBM Enterprise also shares a common purpose of perpetuating use of insulin list prices as the basis payments in the pharmaceutical industry. With respect to the Manufacturer Defendants, these corporations would not be able to market large spreads to the PBM Defendants in exchange for favorable formulary positions without the use of the inflated list prices as the basis for TPP payments in the pharmaceutical industry. The PBM Defendants share this common purpose because, without the use of the inflated list prices, their profits on the spread between list and net prices would collapse. As a result, PBM Defendants have, with

the knowing and willful participation and assistance of the Manufacturer Defendants, engaged in hidden profit-making schemes falling into four general categories: (i) they pocket what their TPP clients pay them as service fees for processing prescriptions and operating mail order pharmacies; (ii) they keep the difference between what they pay pharmacies for drugs, which is negotiated as a percentage of list price plus dispensing costs, and what TPPs pay them, which is a higher percentage of list price plus dispensing costs; (iii) they profit from selling prescription drugs to TPPs through the mail order pharmacies that they own and operate; and (iv) they retain the entirety of undisclosed and/or hidden rebates they receive..

395. Each of the Manufacturer-PBM Insulin Pricing Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between each Manufacturer Defendant and each PBM Defendant that is an associate. As to each of the Manufacturer-PBM Insulin Pricing Enterprises, there is a common communication network by which each Manufacturer Defendant and each PBM Defendant share information on a regular basis, including information regarding the Insulin Drug list prices and net prices. As to each of the Manufacturer-PBM Insulin Pricing Enterprises, each Manufacturer Defendant and each PBM Defendant functioned as a continuing unit. At all relevant times, each of the Manufacturer-PBM Insulin Pricing Enterprises was

operated by the specific Manufacturer Defendant and PBM Defendant for criminal purposes, namely, carrying out the pricing scheme.

396. At all relevant times, PBM Defendants have been aware of the Manufacturer-PBM Insulin Pricing Enterprises' conduct, have been knowing and willing participants in that conduct, and have reaped profits from that conduct. PBM Defendants strike rebate deals with Manufacturer Defendants to conceal the true net prices of the Insulin Drugs and profit from the inflated list prices. PBM Defendants have represented to the public that the rebates they negotiate save TPPs (including TPP Plaintiffs and Class members) money on prescriptions. But they have known that the increasing spreads did not and do not actually decrease the net prices of the Insulin Drugs: the list prices were and are falsely inflated while the net prices have remained, more or less, constant. But for the Manufacturer-PBM Insulin Pricing Enterprises' common purpose of enlarging the hidden spreads between net and list price, PBM Defendants would have had the incentive to disclose the fraudulence of Manufacturer Defendants' list prices. By failing to disclose this information, PBM Defendants and Manufacturer Defendants perpetuated the conduct of the Manufacturer-PBM Insulin Pricing Enterprises.

397. Further, the PBM Defendants took instructions and commands from the Manufacturer Defendants regarding use of the Insulin Drug list prices, not only so that they could keep part of the spread, but also so as to continue to earn from the

Manufacturer Defendants: (i) *access rebates* for placement of products on their formulary; (ii) *market share rebates* for garnering higher market share than established targets; (iii) *administrative fees* for assembling data to verify market share results; and (iv) *other fees and grants* in an effort to promote products.

398. In order to garner all of these fees from Manufacturer Defendants, each PBM Defendant and each Manufacturer Defendant meet on a regular basis to discuss Insulin Drug prices, spreads, marketing opportunities, and coordination of all of the above.

399. There is a common communication network between each PBM Defendant and each Manufacturer Defendant for the purpose of implementing the pricing and kickback scheme and for the exchange of financial rewards for PBM Defendants activities that benefit Manufacturer Defendants.

400. At all relevant times, each one of PBM Defendants was aware of the pricing and kickback scheme, was a knowing and willing participant in that scheme, and reaped profits from that scheme.

401. For purposes of this count, the Manufacturer-PBM Insulin Pricing Enterprises are further identified as follows:

a. The Eli Lilly-PBM Enterprises

402. The Eli Lilly-PBM Enterprises are three separate associations-in-fact consisting of Eli Lilly, including its directors, employees, and agents, and each of

the PBM Defendants that administers purchases of Eli Lilly's Humalog, Humulin, and Basaglar, including its directors, employees, and agents: (1) the Eli Lilly-CVS Caremark association-in-fact enterprise; (2) the Eli Lilly-Express Scripts association-in-fact enterprise; and (3) the Eli Lilly-OptumRx association-in-fact enterprise. Each of the Eli Lilly-PBM Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of exchanges kickbacks or "rebates" for preferred formulary positions for Eli Lilly's Humalog, Humulin, and Basaglar as treatments for Type 1 and Type 2 diabetes to the exclusion of competitor products. Each of the Eli Lilly-PBM Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Eli Lilly and CVS Caremark, Eli Lilly and Express Scripts, and Eli Lilly and OptumRx. As to each of these Eli Lilly-PBM Enterprises, there is a common communication network by which Eli Lilly and CVS Caremark, Eli Lilly and Express Scripts, and Eli Lilly and OptumRx share information on a regular basis. As to each of these Eli Lilly-PBM Enterprises, Eli Lilly and CVS Caremark, Eli Lilly and Express Scripts, and Eli Lilly and OptumRx function as continuing but separate units. At all relevant times, each of the Eli Lilly-PBM Enterprises was operated and conducted by Eli Lilly and the specific PBM Defendant for criminal purposes, namely, carrying out the pricing and kickback scheme.

b. The Novo Nordisk-PBM Insulin Pricing Enterprises

403. The Novo Nordisk-PBM Insulin Pricing Enterprises are three separate associations-in-fact consisting of Novo Nordisk, including its directors, employees and agents, and each of the PBMs that administered purchases of Novo Nordisk's Fiasp, Novolog, Levemir, Novolin, and Tresiba, including its directors, employees, and agents: (1) the Novo Nordisk-CVS Caremark association-in-fact enterprise; (2) the Novo Nordisk-Express Scripts association-in-fact enterprise; and (3) the Novo Nordisk-OptumRx association-in-fact enterprise. Each of the Novo Nordisk-PBM Insulin Pricing Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of exchanges kickbacks or "rebates" for preferred formulary positions for Novo Nordisk's Levemir, Tresiba, Novolin, Fiasp, and Novolog, as treatments for Type 1 and Type 2 diabetes to the exclusion of competitor products. Each of the Novo Nordisk-PBM Insulin Pricing Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Novo Nordisk and CVS Caremark, Novo Nordisk and Express Scripts, and Novo Nordisk and OptumRx. As to each of these Novo Nordisk-PBM Insulin Pricing Enterprises, there is a common communication network by which Novo Nordisk and CVS Caremark, Novo Nordisk and Express Scripts, and Novo Nordisk and OptumRx share information on a regular basis. As

to each of these Novo Nordisk-PBM Insulin Pricing Enterprises, Novo Nordisk and CVS Caremark, Novo Nordisk and Express Scripts, and Novo Nordisk and OptumRx function as continuing but separate units. At all relevant times, each of the Novo Nordisk-PBM Insulin Pricing Enterprises was operated and conducted by Novo Nordisk and the specific PBM Defendant for criminal purposes, namely, carrying out the pricing scheme.

c. The Sanofi-PBM Insulin Pricing Enterprises

404. The Sanofi-PBM Insulin Pricing Enterprises are three separate associations-in-fact consisting of Sanofi, including its directors, employees and agents, and each of the PBMs that administered purchases of Sanofi's Apidra, Lantus, and Toujeo, including its directors, employees, and agents, and Sanofi, including its directors, employees and agents: (1) the Sanofi-CVS Caremark association-in-fact enterprise; (2) the Sanofi-Express Scripts association-in-fact enterprise; and (3) the Sanofi-OptumRx association-in-fact enterprise. Each of the Sanofi-PBM Insulin Pricing Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of exchanges kickbacks or "rebates" for preferred formulary positions for Sanofi's Lantus, Toujeo, and Apidra, as treatments for Type 1 and Type 2 diabetes to the exclusion of competitor products. Each of the Sanofi-PBM Insulin Pricing Enterprises has a systemic linkage because

there are contractual relationships, financial ties, and continuing coordination of activities between Sanofi and CVS Caremark, Sanofi and Express Scripts, and Sanofi and OptumRx. As to each of these Sanofi-PBM Insulin Pricing Enterprises, there is a common communication network by which Sanofi and CVS Caremark, Sanofi and Express Scripts, and Sanofi and OptumRx share information on a regular basis. As to each of these Sanofi-PBM Insulin Pricing Enterprises, Sanofi and CVS Caremark, Sanofi and Express Scripts, and Sanofi and OptumRx function as continuing but separate units. At all relevant times, each of the Sanofi-PBM Insulin Pricing Enterprises was operated and conducted by Sanofi and the specific PBM Defendant for criminal purposes, namely, carrying out the pricing and kickback scheme.

405. The Manufacturer-PBM Insulin Pricing Enterprises (Eli Lilly-CVS Caremark, Eli Lilly-Express Scripts, Eli Lilly-OptumRx, Novo Nordisk-CVS Caremark, Novo Nordisk-Express Scripts, Novo-Nordisk-OptumRx, Sanofi-CVS Caremark, Sanofi-Express Scripts, and Sanofi-OptumRx) knowingly made material misrepresentations, including omissions, to Class members in furtherance of the fraudulent scheme regarding:

- a. The net prices of the Insulin Drugs;¹⁶²

¹⁶² The Eli Lilly-PBM Enterprises made these misrepresentations with respect to Humalog, Humulin, and Basaglar. The Novo Nordisk-PBM Insulin Pricing Enterprises made these representations with respect to Fiasp, Novolog, Levemir,

- b. The reasons for the Insulin Drug price increases;
- c. PBM Defendants' receipt of kickbacks in the form of purported rebates, fees, or other payments for formulary placement unconnected to services rendered;
- d. The existence, purpose, and amount of the bribes and kickbacks and other monies paid to PBM Defendants;
- e. The effect of the rebates, fees, and other payments on PBM Defendants' development, management, and administration of formularies;
- f. The extent to which the net prices of the Insulin Drugs departed from their artificially-inflated list prices;
- g. That the Insulin Drugs' list prices served as a reasonable and fair basis for Other Direct Purchaser and TPP payments for Insulin Drugs;
- h. The extent to which the Manufacturer Defendants and the PBM Defendants negotiated the rebates discounting the list prices of the Insulin Drugs in good faith and for a proper purpose;
- i. Whether the rebates—as opposed to lower list prices—saved TPPs and the general public money;
- j. Whether the “preferred” formulary status of the Insulin Drugs reflects the drugs’ safety, efficacy, or cost-effectiveness, as determined by the PBM Defendants’ formulary committees;
- k. Whether the Insulin Drugs would have been placed in “preferred” formulary positions absent the spreads;
- l. Whether that the “administrative fees” Manufacturer Defendants paid to PBM Defendants were not for administrative services performed by PBM Defendants in relation to the processing, invoicing, and collection of rebates; and

Novolin, and Tresiba. The Sanofi-PBM Enterprises made these misrepresentations with respect to Apidra, Lantus, and Toujeo.

m. The extent to which the pricing schemes forced Plaintiffs and Class members to incur additional expenses for their Insulin Drug prescriptions.

406. Manufacturer Defendants alone could not have accomplished the purposes of the Manufacturer-PBM Insulin Pricing Enterprises without the assistance of PBM Defendants. For Manufacturer Defendants to profit from the scheme, PBM Defendants needed to convince TPPs, like TPP Plaintiffs and similarly situated TPPs, to select their formularies, on which varying Insulin Drugs were given favorable treatment. And PBM Defendants did so by making material misrepresentations and omissions (including to TPP Plaintiffs, potential clients, and investors) that they secured lower prices and by omitting and concealing the bribes, kickbacks, rebates, fees and scheme. The lower prices were illusory, the result of a deliberate scheme to create large spreads without lowering net prices when in reality, Manufacturer Defendants were inflating list prices to fund bribes and kickbacks to PBM Defendants for favorable formulary placement. Without these material misrepresentations and omissions and concealment, the Manufacturer-PBM Enterprise could not have achieved its common purpose.

407. The impacts of the Manufacturer-PBM Insulin Pricing Enterprises are still in place, i.e., the increased spreads between the benchmark and net prices of the Insulin Drugs are still being maintained. As described herein, the bribes and kickbacks are an essential part of the Manufacturer-PBM Insulin Pricing Enterprises

and are embedded in the ongoing Insulin Drug prices. This conduct constitutes a threat of continued criminal activity.

408. The foregoing evidences that Manufacturer Defendants and PBM Defendants were each willing participants in the Manufacturer-PBM Insulin Pricing Enterprises, had a common fraudulent purpose and interest in the objective of the scheme, and functioned within a structure designed to effectuate the Enterprises' purposes, i.e., to increase profits for both Manufacturer Defendants and PBM Defendants through kickbacks to PBM Defendants and continued formulary status without net price reductions from Manufacturer Defendants, preserving and increasing Manufacturer Defendants' profits.

3. The Manufacturer-PBM Insulin Pricing RICO Enterprises' Use of the U.S. Mails and Interstate Wire Facilities

409. Each of the Manufacturer-PBM Insulin Pricing Enterprises engaged in and affected interstate commerce because they engage in the following activities across state boundaries: the sale, purchase and/or administration of the Insulin Drugs; the setting of the prices of the Insulin Drugs; and/or the transmission and/or receipt of sales and marketing literature; and/or the transmission to patients of individual prescriptions for the Insulin Drugs by mail order pharmacies; and/or the transmission and/or receipt of invoices, statements, and payments related to the use or administration of the Insulin Drugs. During the Class period, the Manufacturer-

PBM Insulin Pricing Enterprises participated administration of the Insulin Drugs to millions of individuals located throughout the United States.

410. During the Class period, Defendants' illegal conduct and wrongful practices were carried out by an array of employees, working across state boundaries, who necessarily relied upon frequent transfers of documents and information and products and funds through the U.S. mails and interstate wire facilities.

411. The nature and pervasiveness of Defendants' pricing and kickback scheme, which was orchestrated out of the corporate headquarters of Defendants, necessarily required those headquarters to communicate directly and frequently by the U.S. mails and by interstate wire facilities between Manufacturer Defendants and PBM Defendants.

412. Most of the precise dates of Defendants' uses of the U.S. mails and interstate wire facilities (and corresponding RICO predicate acts of mail and wire fraud) have been hidden and cannot be alleged without access to these Defendants' books and records. Indeed, an essential part of the successful operation of the pricing scheme alleged herein depended upon secrecy, as alleged above. And Defendants took deliberate steps to conceal their wrongdoing. However, Plaintiffs can generally describe the occasions on which the RICO predicate acts of mail fraud and wire fraud occurred, and how those acts were in furtherance of the pricing scheme.

413. Defendants' use of the U.S. mails and interstate wire facilities to perpetrate the pricing scheme involved thousands of communications throughout the Class period including, inter alia:

- a. Marketing materials about the list prices for the Insulin Drugs and the available spreads, which Manufacturer Defendants sent to PBM Defendants located across the country;
- b. Written and oral representations of the Insulin Drug list prices that the Manufacturer Defendants made at least annually and, in many cases, several times during a single year;
- c. Thousands of written and oral communications discussing, negotiating, and confirming the placement of a Manufacturer Defendant's Insulin Drugs on a particular PBM Defendant's formulary;
- d. Written and oral representations regarding information or incentives designed to lessen the prices that each of the PBM Defendants paid for the Insulin Drugs, and/or to conceal those prices or the pricing scheme;
- e. Written communications, including checks, relating to rebates, kickbacks, or other financial inducements paid to each of the PBM Defendants to persuade them to advocate for one Manufacturer Defendant's Insulin Drug over a competitor's product;
- f. Written and oral communications with U.S. government agencies and private insurers that fraudulently misrepresented what the list prices were, or that were intended to deter investigations into the true nature of the list prices or to forestall changes to reimbursement based on something other than list prices;
- g. Written and oral communications with health insurers and patients;
- h. Transmission of list prices from manufacturers to third parties;

- i. Transmission of invoices, statements, and payments related to the use, administration, and/or purchase of the Insulin Drugs;
- j. Receipts of money on tens of thousands of occasions through the U.S. mails and interstate wire facilities—the wrongful proceeds of Defendants' pricing scheme; and
- k. In addition to the above-referenced RICO predicate acts, Defendants' corporate headquarters have communicated through use of the U.S. mails and by interstate wire facilities with their various local headquarters or divisions, in furtherance of the pricing scheme. These mailings include certain documents referenced in this Complaint.

4. Conduct of the RICO Enterprises' Affairs

414. During the Class period, each of the Manufacturer Defendants has exerted control over the Manufacturer-PBM Insulin Pricing Enterprises with which they were associated and, in violation of Section 1962(c) of RICO, each of the Manufacturer Defendants have conducted or participated in the conduct of the affairs of those association-in-fact RICO enterprises, directly or indirectly. Such participation was carried out in the following ways:

- a. Each of the Manufacturer Defendants has directly controlled the list prices for their respective Insulin Drugs, which determine the amounts of rebates, administrative fees, and other payments PBM Defendants receive as compensation in exchange for formulary placement;
- b. Each of the Manufacturer Defendants directly controlled the list prices of their Insulin Drugs they publicly reported;
- c. Each of the Manufacturer Defendants has directly controlled the creation and distribution of marketing, sales, and other materials used to inform each of PBM Defendants of the profit potential of its Insulin Drugs;

- d. Each of the Manufacturer Defendants has relied upon its employees and agents to promote the pricing scheme through the U.S. mails, through interstate wire facilities, and through direct contacts with providers and PBM Defendants; and
- e. Each of the Manufacturer Defendants has controlled and participated in the affairs of the Manufacturer-PBM Insulin Pricing Enterprises with which it is associated by providing kickbacks and bribes falsely labeled as rebates, administrative fees, or other inducements to place that Manufacturer Defendant's Insulin Drug(s) on a PBM Defendant's formulary or advocate the use of a certain Insulin Drug. These inducements include the Manufacturer Defendants' payment to PBM Defendants of: (i) access rebates for placement of products on the PBM Defendants' formulary; (ii) market share rebates for garnering higher market share than established targets; (iii) administrative fees for assembling data to verify market share results; and (iv) other fees and grants. Although PBM Defendants typically agree to share rebates in some form with clients, they usually refuse to disclose specific rebate amounts to TPPs, such as TPP Plaintiffs and Class members. Instead, the PBMs typically disclose rebates in an aggregate compared to performance standards, thereby preventing the TPPs, including the TPP Plaintiffs and Class members, from learning the true number of rebates that the PBM Defendant has received in connection with the Insulin Drugs. Such a lack of transparency obfuscates the delta between Manufacturer Defendants' list prices and their net prices so that the TPPs, including TPP Plaintiffs and Class members, have no way to ascertain whether the prices they are paying for the Insulin Drugs are fair and competitive.
- f. Manufacturer Defendants intended that PBM Defendants would (and did) distribute, through the U.S. mail and interstate wire facilities, promotional and other materials which claimed that rebates lowered drug costs for TPPs, like TPP Plaintiffs and Class members;
- g. Manufacturer Defendants represented to the general public, by stating the Insulin Drugs' list prices without stating that these list prices differed substantially from those net prices offered to

PBM Defendants, that the Insulin Drugs' list prices reflected or approximated true prices for those drugs; and

- h. Manufacturer Defendants Published and announced collusive, artificially inflated list price increases and the reasons therefore, but concealing that the increases were to fund the bribes and kickbacks to the PBM Defendants to secure favorable, preferred, or exclusive formulary placement.

415. In violation of Section 1962(c) of RICO, each of the Manufacturer Defendants has conducted and/or participated in the affairs of each of the Manufacturer-PBM Insulin Pricing Enterprises with which they associated by reporting fraudulently inflated list prices for the Insulin Drugs and by misrepresenting to Plaintiffs and Class members through the publication of their list prices that these list prices were reasonable bases for Plaintiffs' and Class members' out-of-pocket payments, thereby inducing Plaintiffs and Class members to pay inflated amounts for the Insulin Drugs.

416. In addition, PBM Defendants specifically have conducted or participated in the conduct of the affairs of their association-in-fact RICO enterprises, by, among other things: (a) misrepresenting and/or concealing from Plaintiffs, Class members, and the public the existence, amount, and purpose of the rebates, administrative fees, and/or other monies from Manufacturer Defendants; (b) misrepresenting and/or concealing from Plaintiffs, Class members, and the public the effect of the rebates, so-called administrative fees, and/or other monies from Manufacturer Defendants on the Insulin Drug list prices; (c) accepting these ill-

gotten rebates and/or fees in exchange for providing Manufacturing Defendants' Insulin Drugs favorable placement on formularies, and (d) selling the Insulin Drugs at artificially inflated prices directly to TPPs via their mail order pharmacies.

5. Defendants' Pattern of Racketeering Activity

417. Each of the Defendants has conducted and participated in the affairs of the respective Manufacturer-PBM Insulin Pricing Enterprises through a pattern of racketeering activity under 18 U.S.C. § 1961, and committed the following violations outlined below knowingly and with the intent to advance the scheme.

418. Defendants' pattern of racketeering has involved thousands, if not hundreds of thousands, of racketeering acts, and has occurred over the period from 2009 through the present. Each of these mailings and interstate wire transmissions constitutes a "racketeering activity" within the meaning of 18 U.S.C. § 1961(1). Collectively, these violations constitute a "pattern of racketeering activity," within the meaning of 18 U.S.C. § 1961(5), in which each Manufacturer Defendant and PBM Defendant intended to defraud Plaintiffs.

419. All of Defendants' racketeering activities amounted to a common course of conduct, with a similar pattern and purposes. The payments of bribes and kickbacks, misrepresentations and omissions, and separate uses of the U.S. mail and/or interstate wires by Defendants and the respective Manufacturer-PBM Insulin Pricing Enterprises in connection with the illegal schemes were substantially related,

had similar intended purposes, involved similar participants and methods of execution, and had similar results affecting similar victims. The racketeering activity constitutes a threat of continuing criminal activity.

420. Defendants have committed the following predicate acts, all constituting racketeering activity under 18 U.S.C. § 1961.

a. Unlawful Kickbacks for Benefit Plan Services in Violation of 18 U.S.C. § 1954

421. More than 54 percent of the individuals in this country receive prescription drug benefits through their employers pursuant to an employee welfare benefit plan as defined in 29 U.S.C. §1002(1).

422. PBM Defendants are legal persons who provide benefit plan services to most of these employee benefit plans.

423. In direct violation of 18 U.S.C § 1954, Manufacturer Defendants paid and PBM Defendants solicited and received bribes, fees, and kickbacks with the intention of influencing the choice of the Insulin Drugs to include in formularies that determine whether and to what extent a particular Insulin Drugs are available to patients whose prescription drug benefits are provided, in whole or in part, pursuant to an employee welfare benefit plan, all in direct violation of 18 U.S.C. §1954, and therefore comprising racketeering activity by the under 18 U.S.C § 1961(1)(B).

b. Unlawful Bribery in Violation of 18 U.S.C. §§ 1952, 666(a), 666(b)

424. For each year during the Class Period, each of PBM Defendants served as agents of certain TPPs which received in excess of \$10,000 in funds from federal health care programs such as Medicare, Medicaid, and CHAMPVA.

425. For each year during the Class Period, each of Manufacturer Defendants paid and each of PBM Defendants solicited and accepted in excess of \$5,000 in “rebates,” “administrative fees,” and other kickbacks from the sale of the Insulin Drugs.

426. Such “rebates,” “administrative fees,” and other kickbacks were corruptly solicited, demanded, paid, and accepted for the purpose of influencing PBM Defendants to cause the Insulin Drugs to be placed on the preferred drug formularies maintained on behalf of such federally funded TPPs and to reward Manufacturer Defendants for doing so.

427. Given that, the pricing and kickback scheme adopted and implemented by the Manufacturer-PBM Insulin Pricing Enterprises constitute a violation of 18 U.S.C. §§ 1952, 666(a), 666(b) and, as such, comprises racketeering activity under 18 U.S.C. § 1961(1)(B).

c. Violations of the AKS Comprising Racketeering Activity under 18 U.S.C. § 1957

428. The commercial bribes and kickbacks paid by Manufacturer Defendants to PBM Defendants in connection with prescriptions funded in whole or in part by federal health care programs such as Medicare, Medicaid, and CHAMPVA totaled well over \$10,000 per year and were deposited in financial institutions that included federally insured banks.

429. The commercial bribes and kickbacks paid by Manufacturer Defendants to PBM Defendants in connection with prescriptions funded in whole or in part by federal health care program such as Medicare, Medicaid, and CHAMPVA were paid and received with the corrupt and unlawful intention of purchasing, and in fact purchasing, formulary placement for the Insulin Drugs and, as such, constituted ongoing violations of the AKS.

430. PBM Defendants knew that the payments that they received from Manufacturer Defendants were derived from payments solicited and received in violation of the AKS and such payments were, in fact, derived from kickback transactions in violation of the AKS.

431. The AKS is a criminal prohibition against payments made purposefully to induce or reward the referral or generation of federal health care business. The Act criminalizes a drug company's offer or payment of anything of value in return for a PBM's placing that manufacturer's drug in a favorable formulary position with

respect to, in whole or part, a federal health care program. This includes a drug manufacturer’s offer or payment to a PBM respecting private, nonfederal business that implicitly or explicitly requires that the PBM place the manufacturer’s drug in a favorable position with respect to a federal health care program. The AKS extends not just to a drug manufacturer’s payment, but also to the solicitation or acceptance of remuneration by PBMs.

432. The OIG and the Secretary of HHS have long warned that “[l]ump sum payments for inclusion in a formulary or for exclusive or restricted formulary status are problematic and should be carefully scrutinized.” 68 F.R. 23731, at 23736 (2003).

433. The purported “discounts” or “rebates” afforded by PBM Defendants to Manufacturer Defendants do not fall within the safe harbor. First, they are neither “discounts” nor “rebates” alone, as they are accompanied by the quid pro quo of getting preferred formulary treatment. Second, the “discounts” or “rebates” do not reduce the manufacturer’s net selling price—to the extent that the manufacturer has increased the benchmark price to make up for an increased “rebate,” all that it has done is created a widened spread from which PBM Defendants can make more money. This is a classic kickback.

434. The conduct of each of the Manufacturer-PBM Insulin Pricing Enterprises, as described herein, amounts to a violation of 18 U.S.C. § 1957 and is racketeering activity as defined in 18 U.S.C. 1961(1)(B).

d. Unlawful Bribery Under the Travel Act and AKS in Violation of 18 U.S.C. § 1952(a) and 42 U.S.C. § 1320a-7b(b)(2)

435. Comprising racketeering activity under 18 U.S.C. § 1961(1)(B), each of the Manufacturer-PBM Insulin Pricing Enterprises have, in violation of 18 U.S.C. § 1952(a), used U.S. mail and wire facilities in interstate commerce to intentionally promote, manage, establish, carry on, and facilitate the unlawful activity of bribery under the laws of the United States and the laws of the state where committed. *See* 18 U.S.C. § 1952(b)(2).

436. Specifically, as alleged immediately above, through the U.S. mail and wire facilities in interstate commerce in violation of the AKS, each Manufacturer Defendant paid bribes to each of PBM Defendants, which PBM Defendants solicited and/or accepted, with the intention of purchasing, and in fact purchasing, formulary placement for Insulin Drugs for which payment may be made in whole or in part under one or more federal health care programs.

e. Mail and Wire Fraud in Violation of 18 U.S.C. §§ 1341, 1343

437. Each of the Defendants has conducted and participated in the affairs of their respective Manufacturer-PBM Insulin Pricing Enterprises through a pattern of

racketeering activity, including acts that are indictable under 18 U.S.C. § 1341, relating to mail fraud, and 18 U.S.C. § 1343, relating to wire fraud. Defendants' pattern of racketeering likely involved thousands, if not hundreds of thousands, of separate instances of use of the U.S. mails or interstate wire facilities in furtherance of their scheme or artifice to defraud for purposes of obtaining money or property. Each of these fraudulent mailings and interstate wire transmissions constitutes a "racketeering activity" within the meaning of 18 U.S.C. § 1961(1)(B). Collectively, these violations constitute a "pattern of racketeering activity," within the meaning of 18 U.S.C. § 1961(5), in which Defendants intended to defraud Plaintiffs, Class members, and other intended victims of the pricing scheme.

438. Specifically, as outlined above, each of the Insulin Drugs have been promoted through the mail and wires, thereby announcing to health plans, including TPP Plaintiffs, Other Direct Purchaser Plaintiffs, and Class members, each Manufacturer Defendant's artificially inflated list price increases but omitting the material fact that the reason for the increased list prices was to fund, increase, and/or recoup each Manufacturer Defendant's bribes and kickbacks to secure formulary placement. Moreover, Defendants have falsely and misleadingly called the bribes and kickbacks to PBM Defendants "rebates"—which have been publicly represented as lowering drug costs—when they are, in fact, bribes and kickbacks to PBM

Defendants for formulary placement, which enabled each Manufacturer Defendant to sell the Insulin Drugs at inflated prices.

439. Defendants' racketeering activities amounted to a common course of conduct, with similar patterns and purposes, intended to deceive Plaintiffs and Class members. Each separate use of the U.S. mails and/or interstate wire facilities employed by each of the Defendants was related, had similar intended purposes, involved similar participants and methods of execution, and had the same results affecting the same victims, including Plaintiffs and Class members. Each of the Defendants has engaged in the pattern of racketeering activity for the purpose of conducting the ongoing business affairs of the respective Manufacturer-PBM Insulin Pricing Enterprises with which each of them is and was associated in fact.

6. Defendants' Motive

440. Defendants' motive in creating and operating the pricing scheme and conducting the affairs of the Manufacturer-PBM Insulin Pricing Enterprises described herein was to fraudulently obtain sales of and profits related to the Insulin Drugs.

441. The pricing scheme was designed to, and did, encourage others, including health care providers, to advocate the use of Manufacturer Defendants' Insulin Drugs. Thus, each of the Manufacturer Defendants used the pricing scheme

to sell more of its drugs, thereby fraudulently gaining sales, marketplace share, and profits.

442. PBM Defendants used the pricing scheme to increase their profits by benefitting from larger spreads between the list prices and net prices of the Insulin Drugs.

7. Damages Caused by Defendants' Pricing Scheme

443. Defendants' violations of federal law and their pattern of racketeering activity have directly and proximately caused Plaintiffs and Class members to be injured in their business or property by overpaying for the Insulin Drugs. Plaintiffs and Class members each directly bought Insulin Drugs from one or more of Defendants, and thus were directly and immediately harmed by Defendants' schemes. Defendants intended and foresaw that Plaintiffs and Class members would pay substantial overcharges due to Defendants' pattern of racketeering activity.

444. Defendants sent billing statements through the U.S. mails or by interstate wire facilities and reported the list prices and other information by the same methods in furtherance of their pricing scheme. Plaintiffs and Class members have overpaid for the Insulin Drugs based on and/or in reliance on reported and false list prices. As previously explained, when a patient fills a prescription for one of the Insulin Drugs at CVS Caremark, Express Scripts, or OptumRx, her health plan is responsible for a portion or nearly all of the medication's cost. And the health plans

pay directly to CVS Caremark, Express Scripts, or OptumRx, members of the Manufacturer-PBM Insulin Pricing Enterprises.

445. The amount of each of payment for the Insulin Drug is tied directly to the Manufacturer Defendants' list prices. No other intermediary in the supply chain has control over or is responsible for the list prices on which payments are based. By setting the list prices of the Insulin Drugs, Defendants are setting the prices Plaintiffs and Class members must pay. Therefore, when each Manufacturer Defendant artificially inflates each Insulin Drug's list price and then uses each Manufacturer-PBM Insulin Pricing Enterprises to sell those Insulin Drugs, they also artificially inflate Plaintiffs' and Class members' payments for those drugs.

446. Though PBM Defendants could have used their control over the development, management, and administration of the formularies and prescription drug programs that their TPPs relied upon to drive down the prices for the Insulin Drugs by forcing Manufacturer Defendants to lower their list prices, PBM Defendants instead leveraged their position to obtain the Manufacturer Defendants' bribes and kickbacks for their own financial benefit and contrary to the economic interests of their TPP clients and plan members.

447. Rather than lower their prices to gain market share via formulary inclusion, Manufacturer Defendants instead engaged in a scheme with PBM Defendants to corrupt the supply chain by artificially inflating list prices in exchange

for preferred formulary placement, shifting the cost of the bribes and kickbacks to purchasers of the Insulin Drugs such as Plaintiffs and Class members and sharing those financial benefits with the PBM Defendants.

448. Absent the payment of bribes and kickbacks, and their achievement through the Insulin Drugs list price increases, Manufacturer Defendants would have been forced to compete for preferred formulary placement through lower prices, as they would in a legitimate market. As the gatekeepers in the supply chain, PBM Defendants could and would have used formulary placement (or exclusion) to penalize manufacturers who raised prices as Manufacturer Defendants did here, rather than perversely rewarding manufacturers who raised prices and inducing them to do so with favorable formulary placement.

449. But for the payment of bribes and kickbacks, and their achievement through list price increases, the Insulin Drugs would have had a lower list price, and Plaintiffs and Class members would have paid less for the Insulin Drugs. Plaintiffs and Class members have overpaid for the Insulin Drugs purchased directly from the Defendants.

450. Defendants' racketeering activity directly and proximately caused Plaintiffs and Class members injuries because Plaintiffs and Class members purchased the Insulin Drugs directly from Defendants. Further, given that Plaintiffs and Class members were and are the most direct and immediate victims of the

unlawful and fraudulent schemes, Plaintiffs and Class members are best situated to vindicate the law and seek recovery for the economic harm caused by Defendants based on the substantial overcharges for the Insulin Drugs.

451. By virtue of these violations of 18 U.S.C. § 1962(c), under the provisions of Section 1964(c) of RICO, Defendants are jointly and severally liable to Plaintiffs and Class members for three times the damages that Plaintiffs and Class members have sustained, plus the costs of bringing this suit, including reasonable attorneys' fees.

452. By virtue of these violations of 18 U.S.C. § 1962(c), under the provisions of Section 1964(c) of RICO, Plaintiffs and Class members further seek injunctive relief against Defendants for their fraudulent reporting of their list prices, plus the costs of bringing this suit, including reasonable attorneys' fees. Absent an injunction, the effects of this fraudulent conduct will continue. Plaintiffs will continue purchasing the Manufacturer Defendants' Insulin Drugs, and Plaintiffs and Class members will continue to pay based on Defendants' fraudulent benchmark prices. In a country where tens of thousands of citizens cannot afford their medications needed to treat diabetes, or where the expense of such drugs is a great burden on millions, and there is no cure for diabetes, any continuing fraudulent conduct is a serious matter that calls for injunctive relief as a remedy. Plaintiffs will

seek injunctive relief, including an injunction against Defendants, to prevent them from reporting benchmark prices that do not approximate their true net prices.

B. COUNT TWO
VIOLATIONS OF RICO, 18 U.S.C. § 1962(d)
(Against All Defendants on behalf of the all Plaintiffs and the Class)

453. Plaintiffs incorporates by reference the allegations contained in the preceding paragraphs.

454. Defendants have violated § 1962(d) by agreeing and conspiring to violate 18 U.S.C. § 1962(c). The object of this conspiracy has been and is to conduct or participate in, directly or indirectly, the conduct of the affairs of the § 1962(c) Manufacturer-PBM Insulin Pricing Enterprises described previously through a pattern of racketeering activity.

455. As set forth in detail above, Defendants have engaged in numerous overt and predicate unlawful and fraudulent acts, constituting a pattern of racketeering activity, in furtherance of the conspiracy. Defendants intended to engage in the schemes, resulting in Plaintiffs and Class members paying substantial overcharges for the Insulin Drugs. Defendants knew that their predicate acts were part of a pattern of racketeering activity and agreed to the commission of those acts to further the schemes outlined herein.

456. The nature of Defendants' acts, material misrepresentations, and omissions in furtherance of the conspiracy, as set forth in detail above, gives rise to

an inference that they not only agreed to the objective of an 18 U.S.C. § 1962(d) violation of RICO by conspiring to violate 18 U.S.C. § 1962(c), but that they were aware that their ongoing unlawful and fraudulent acts have been and are part of an overall pattern of racketeering activity.

457. Defendants have engaged (and continue to engage) in the commission of overt acts in furtherance of the Manufacturer-PBM Insulin Pricing Enterprise schemes, including the following unlawful racketeering predicate acts (as outlined in detail above):

- Multiple instances of unlawful bribery and kickbacks in violation of 18 U.S.C. §§ 666(a), 666(b), 1952, 1954, 1957, 1961(1), and 42 U.S.C. 1320a-7b(b)(2);
- Multiple instances of mail fraud in violation of 18 U.S.C. § 1341; and
- Multiple instances of wire fraud in violation of 18 U.S.C. § 1343.

458. Defendants' violations of the above federal laws and the effects thereof outlined in detail above are continuing and will continue. As a direct and proximate result of these violations, Plaintiffs and Class members have been injured in their business and property; Plaintiffs and Class members have made at least millions of dollars in overpayments for the Insulin Drugs purchased directly from the Defendants that they would not have paid but for Defendants' conspiracies to violate 18 U.S.C. § 1962(c).

459. By virtue of these violations of 18 U.S.C. § 1962(d), Defendants are, respectively, jointly and severally liable to Plaintiffs and Class members for three

times the damages Plaintiffs and Class members have sustained, plus the costs of bringing this suit, including reasonable attorneys' fees.

460. By virtue of these violations of 18 U.S.C. § 1962(d), under the provisions of Section 1964(d) of RICO, Plaintiffs and Class members further seek injunctive relief against Defendants for their fraudulent reporting of list prices and kickback scheme, plus the costs of bringing this suit, including reasonable attorneys' fees. Absent an injunction, the effects of this fraudulent and unlawful conduct will continue. Plaintiffs and Class members will continue purchasing Manufacturer Defendants' Insulin Drugs, and Plaintiffs and Class members will continue to pay based on Defendants' fraudulent list prices. In a country where tens of thousands of citizens cannot afford their medication needed to treat diabetes, or where the expense of such drugs is a great burden on millions, and there is no cure for diabetes, any continuing fraudulent and unlawful misconduct is a serious matter that calls for injunctive relief as a remedy.

C. COUNT THREE
VIOLATION OF THE ROBINSON-PATMAN ACT, 15 U.S.C. § 13(c)
(Against All Defendants on behalf of all Plaintiffs¹⁶³ and the Class)

461. Plaintiffs incorporates by reference the allegations contained in the preceding paragraphs.

¹⁶³ Plaintiffs acknowledge that this Court's July 2021 order in *In re: Direct Purchaser Insulin Pricing Litigation* dismissed without prejudice the Section 2(c) Robinson-Patman Act claims brought by Other Direct Purchaser Plaintiffs based

462. Plaintiffs assert this claim against Defendants on behalf of themselves and the Class.

463. Section 2(c) of the Robinson-Patman Act provides:

It shall be unlawful for any person engaged in commerce, in the course of such commerce, to pay or grant, or to receive or accept, anything of value as a commission, brokerage, or other compensation, or any allowance or discount in lieu thereof, except for services rendered in connection with the sale or purchase of goods, wares, or merchandise, either to the other party to such transaction or to an agent, representative, or other intermediary therein where such intermediary is acting in fact for or in behalf, of is subject to the direct or indirect control, of any party to such transaction other than the person by whom such compensation is so granted or paid.

15 U.S.C. § 13(c).

464. By engaging in the kickback and commercial bribery scheme described herein, Defendants have engaged in commercial bribery in violation of Section 2(c) of the Robinson-Patman Act, 15 U.S.C. § 13(c).

465. The PBM Defendants owed a legal duty to the Plaintiffs and the Class Members to negotiate rebates and fees and construct formularies for the benefit of the Plaintiffs and Class Members. The PBM Defendants have held themselves out

solely on the Court's conclusion that these plaintiffs lacked statutory standing to pursue the claim. *See Case No. 3:20-cv-3426, ECF No. 158 at 15-16.* Consistent with the Other Direct Purchaser Plaintiffs' Second Amended Complaint, these plaintiffs are including their Robinson-Patman claim in this consolidated amended pleading to preserve all rights to pursue the cause of action should the Court of Appeals reverse or vacate the order. *See SAC at n.2, Case No. 3:20-cv-3426, ECF No. 261.* Accordingly, Plaintiffs, if necessary, will revise the class definition at class certification consistent with the claims legally available at that time.

as having superior knowledge and expertise about the pharmaceutical industry and the negotiation of prices and rebates with drug manufacturers. Because of their superior knowledge and expertise, the TPP Plaintiffs retained the PBM Defendants to negotiate on their behalf for their benefit with Manufacturer Defendants with regard to formulary placement, price and rebates or fees in connection with the sale of drugs, including the Insulin Drugs. The TPP Plaintiffs and the Defendants all understood that the purpose of TPP Plaintiffs' retention of a PBM was to assist the TPPs to reduce the costs associated with providing prescription drugs to plan members.

466. The TPP Plaintiffs trusted the PBM Defendants to make formulary placement decisions, including for the Insulin Drugs, in the best interest of TPP Plaintiffs and to help them manage and reduce the cost of acquiring drugs for their plan members. The TPP Plaintiffs relied on the PBM Defendants to do so.

467. By accepting and retaining unearned rebates and fees from the Manufacturer Defendants or by having their respective Rebate Aggregator agents/designees accept and retain unearned and undisclosed rebates and "fees" on behalf of and for their benefit, the PBM Defendants breached their duty to the TPP Plaintiffs.

468. Zinc, Ascent and Emisar acted as the agents for and at the direction of their respective PBM Defendant in negotiating price, rebates and purported "fees"

with the Manufacturer Defendants in connection with sale of the Insulin Drugs to the TPP Plaintiffs. The rebates and purported “fees” which Zinc, Ascent and Emisar received from the Manufacturer Defendants in connection with the sale of the Insulin Drugs were received on behalf of and for the benefit of the respective PBM Defendants.

469. The Manufacturer Defendants also knew and understood that Zinc, Ascent and Emisar were acting as the agents for and at the direction of their respective PBM’s in negotiating price, rebates and purported “fees” for the acquisition of the Insulin Drugs from the Manufacturer Defendants. The Manufacturer Defendants further knew and understood that the rebates and purported “fees” which they paid to Zinc, Ascent, and Emisar in connection with the sale of the Insulin Drugs were being paid for the benefit and on behalf of the respective PBM Defendants and in exchange for favorable placement by the PBM Defendants of the Manufacturer Defendants’ Insulin Drugs on the TPP formularies and that such placement was contrary to the interests of the TPP Plaintiffs.

470. Had the Manufacturer Defendants not paid the unearned and undisclosed rebates and purported “fees” (i.e. the bribes) to the PBM Defendants and their Rebate Aggregator agents/designees, the PBM’s would not have granted the unwarranted and favorable formulary placement to the Manufacturer Defendants’ Insulin Drugs.

471. The Manufacturer Defendants artificially increased the price for the Insulin Drugs by engaging in the commercial bribery and kickback scheme described herein.

472. PBM Defendants sought, and Manufacturer Defendants paid, kickbacks, bribes, and other unearned sums to the PBM Defendants, who are the agents and/or fiduciaries of the TPP Plaintiffs and similarly situated TPP Class members, that were not disclosed to TPP Plaintiffs or TPP Class members.

473. At the time the kickbacks, bribes, and other unearned sums were paid by the Manufacturer Defendants to the PBM Defendants, PBM Defendants were under the control of and/or working on behalf of the TPP Plaintiffs and similarly situated TPP Class members. The payments accordingly crossed the buyer/seller line.

474. The kickbacks, bribes, and other unearned sums were paid to the PBM Defendants, who are the agents and/or fiduciaries of the TPP Plaintiffs and similarly situated TPP Class members, without the consent of the TPP Plaintiffs or TPP members of the Class.

475. The kickbacks, bribes, and other unearned sums were intended to influence the PBM Defendants to give the Manufacturer Defendants' Insulin Drugs favorable placements on formularies and to continue participating in the illegal scheme to keep prices for the Insulin Drugs artificially high.

476. Pursuant to the kickback and commercial bribery scheme described above, Defendants created illegal inducements that resulted in artificially inflated prices.

477. As a result of Defendants' unlawful conduct, Plaintiffs and Class members purchased Insulin Drugs at artificially inflated prices as a result of undisclosed and unearned fees and rebates.

478. There is no appropriate or legitimate business justification for Defendants' conduct. The payments to the PBMs were not for any services rendered.

479. Defendants' unlawful conduct has resulted in competitive injury to Plaintiffs and Class members by unduly restraining, hindering, suppressing, and/or eliminating competition in the sale of commodities in interstate commerce.

480. As a direct and proximate result of Defendants' unlawful actions detailed herein, Plaintiffs and Class members suffered substantial economic losses in the form of overcharges for the Insulin Drugs.

481. Plaintiffs and Class members are entitled to recover treble damages and costs of suit, including reasonable attorneys' fees, pursuant to Section 4(a) of the Clayton Act, 15 U.S.C. § 15(a).

XI. DEMAND FOR JUDGMENT

WHEREFORE, Plaintiffs, on behalf of themselves and the proposed Class, respectfully demand that this Court:

- A. Determine that this action may be maintained as a class action pursuant to Federal Rules of Civil Procedure 23(a), (b)(2) and (b)(3), and direct that reasonable notice of this action, as provided by Federal Rule of Civil Procedure 23(c)(2), be given to the Class, and declare Plaintiffs as the representatives of the Class;
- B. Enter judgments against Defendants and in favor of Plaintiffs and the Class;
- C. Award Plaintiffs and the Class damages (i.e., three times the overcharges) in an amount to be determined at trial, or, in the alternative, treble the amount of the unearned and undisclosed rebates or bribes all;
- D. Award Plaintiffs and the Class their costs of suit, including reasonable attorneys' fees and costs as provided by law; and
- E. Enjoin the Manufacturer Defendants from continuing to report artificially inflated list prices that do not approximate their true net prices to the PBM Defendants.
- F. Award such further and additional relief as the case may require and the Court may deem just and proper under the circumstances.

XII. JURY DEMAND

Pursuant to Federal Rule of Civil Procedure 38, Plaintiffs, on behalf of themselves and the proposed Class, demand a trial by jury on all issues so triable.

Dated: October 4, 2024

Respectfully submitted,

/s/ Matthew F. Gately

Matthew F. Gately

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